HEALTH PRODUCTS CONTAINING CANNABIS OR FOR USE WITH CANNABIS:

Guidance for the *Cannabis Act*, the *Food and Drugs Act*, and Related Regulations

Government of Canada
Gouvernement du Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Les produits de santé contenant du cannabis ou à utiliser avec du cannabis : Lignes directrices pour la Loi sur le cannabis, la Loi sur les aliments et drogues, et les règlements connexes

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This guide sets out the regulatory framework for health products containing cannabis or for use with cannabis that are approved under the *Food and Drugs Act*. This framework includes requirements for licensed activities under the *Cannabis Act* and the *Food and Drugs Act* and their respective regulations, rules that apply to the health products themselves, and obligations for certain healthcare professionals. Further information about the process to obtain the relevant licences can be requested from Health Canada.

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Disclaimer: This document should be read in conjunction with relevant sections of the *Cannabis Act*, the *Food and Drugs Act* and their respective regulations. In the case of any discrepancies between this document and the legislation, the latter shall prevail.

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1 INTRODUCTION

1.1 Purpose

To inform stakeholders about the regulatory framework for health products containing cannabis or for use with cannabis that are approved under the *Food and Drugs Act*. This framework includes requirements for licensed activities, rules that apply to the health products themselves, and obligations for certain healthcare professionals.

1.2 Background

Prior to the coming into force of the *Cannabis Act* on October 17, 2018, cannabis is regulated as both a controlled substance under the *Controlled Drugs and Substances Act* (CDSA), as well as a drug under the *Food and Drugs Act* (FDA). Under this legislative framework, activities with cannabis are generally prohibited, unless authorized under certain regulations (e.g., *Access to Cannabis for Medical Purposes Regulations (ACMPR), Narcotic Control Regulations (NCR), Food and Drug Regulations,* and *Industrial Hemp Regulations (IHR)*).

Together, the CDSA and the FDA establish strict parameters for the production, possession, distribution, and sale of health products containing cannabis. Cannabis could be included in prescription drugs, subject to the same requirements as other narcotics. In addition, certain parts of the cannabis plant that generally do not contain psychoactive cannabinoids could be included in Natural Health Products (NHPs) or Veterinary Health Products (VHPs) under certain conditions.

Within this legislative framework, two prescription drugs containing cannabis and one synthetic cannabinoid have been approved for sale. Sativex contains tetrahydrocannabinol (THC) and cannabidiol (CBD), and Marinol contains THC. Sativex is available to Canadian patients, but Marinol was voluntarily withdrawn from the market by its manufacturer. Drugs containing the synthetic cannabinoid nabilone have also been approved. Nabilone, a synthetic cannabinoid which does not exist in nature, is not captured by the definition of cannabis in the *Cannabis Act*, and will remain scheduled under the CDSA as a narcotic. There are currently no authorized veterinary drugs containing cannabis.

As of March 2018, roughly 220 NHPs containing permitted parts of the cannabis plant, and no more than 10 parts per million THC, have also been approved with general health claims or for treating minor conditions. 19 VHPs containing non-viable seed derivatives (as a dried or as an extract preparation with no more than 10 parts per million THC) have also been approved with general health claims.

1.3 Overview of New Legislative Framework

When the *Cannabis Act* comes into force, cannabis will be removed from the CDSA, and be subject to restrictions under the new legislative framework. Upon its coming into force, the *Cannabis Act* will maintain a partnership with the FDA for regulating health products that is similar to what exists between the CDSA and the FDA, achieving the distinct objectives of two pieces of legislation in a coordinated way.

The *Cannabis Act* and its regulations control the production, distribution, sale and possession of cannabis across Canada. For greater clarity, products containing cannabis can be considered to fall into one of three different categories:

- **Cannabis for non-medical purposes**—obtained from provincially and territorially licenced sellers, with no health claims or pre-market review for safety and efficacy
- **Cannabis for medical purposes**—obtained via a health care practitioner's authorization for human use, with no health claims or premarket review for safety and efficacy
- **Health products containing cannabis or for use with cannabis**—products, such as prescription drugs and medical devices that are marketed with health claims and subject to a premarket authorization by Health Canada

Health products containing cannabis or for use with cannabis will remain subject to a number of requirements under the FDA to ensure appropriate controls for safety, efficacy, and quality, while separate requirements under the *Cannabis Act* will protect against risks to public health and safety, including diversion to the illegal market.

The Cannabis Regulations establish a framework that allows existing health products containing cannabis or for use with cannabis to remain on the market. These regulations complement existing pathways under the FDA for the review and approval of new health products. Similar to the dual licencing requirements that exist for the production and distribution of prescription drugs with cannabis under the the CDSA and the FDA, a dual-licencing regime is being established to meet the objectives of the *Cannabis Act*. From a patient perspective, Canadians will continue to be able to access prescription drugs containing cannabis in the same way as they do now: through a prescription filled by their pharmacist.

Non-Medical *(Cannabis Act)*	**Medical** *(Cannabis Act)*	**Health Products with Cannabis** *(Cannabis Act* & FDA)
• Limited classes initially (fresh, dried, oil, plants and seeds); edibles and concentrates 1 year later • Health care practitioner authorization not required • **No pre-market review** for safety, efficacy • Quality and security requirements under the *Cannabis Act* • **CANNOT** make health claims	• Same limited classes non-medical (fresh, dried, oil, plants, and seeds); edibles and concentrates 1 year later • Health care practitioner authorization required. • **No pre-market review** for safety, efficacy • Quality and security requirements under *Cannabis Act* • **CANNOT** make health claims	• No restrictions on product classes that may be approved under FDA (e.g. dosage forms for prescription drugs) • Practitioner oversight required (i.e., Rx drugs) • **Pre-market review** for safety, efficacy and quality under FDA • Manufacturing subject to quality and security requirements under the FDA and *Cannabis Act* • **CAN** make health claims, if authorized

1.4 Scope and Application

This document provides guidance on legislative and regulatory requirements related to health products that will be subject to both the FDA and the *Cannabis Act*. Such health products include:

- prescription drugs containing cannabis;
- medical devices containing cannabis or for use with cannabis;
- Natural Health Products (NHPs) containing parts of the cannabis plant permitted under the *Natural Health Products Regulations* (see section 3.4 for more details); and,
- Veterinary Health Products (VHPs) containing non-viable cannabis seed derivatives that comply with the notification program under the *Food and Drug Regulations*.

It is primarily intended to support organizations and individuals who may be interested in conducting activities that require a licence under the *Cannabis Act* (e.g., production and distribution of drugs containing cannabis), and regulated parties such as pharmacists, practitioners, and individuals in charge of a hospital who are subject to certain requirements. In addition, it also supports all Canadians in understanding this regulatory framework and how it affects the health products that are available to them.

While intended to provide guidance, this document does not provide a comprehensive understanding of all licences or authorizations necessary for activities related to health products containing cannabis or for use with cannabis. The latest information regarding the legislative framework for cannabis, including related guidance documents on Health Canada's cannabis website.

Relevant regulations include:

- the *Cannabis Regulations;*
- the *Industrial Hemp Regulations;*
- the *Food and Drug Regulations;*
- the *Medical Devices Regulations;*
- the *Natural Health Products Regulations (NHPR);* and,
- the *Cannabis Exemption (Food and Drugs Act) Regulations.*

2 HEALTH RESEARCH AND CLINICAL TRIALS WITH CANNABIS

2.1 Requirements for the authorization of a clinical trial

Health Canada recognizes that clinical research is critical to the development of drug products which are safe and effective. An increased availability of authorized drugs provides Canadians with a greater selection of therapeutic options to meet their health needs. High-quality research also helps guide practitioners in evidence-based decision making when prescribing and managing patients using these drugs. The Department encourages ongoing cannabis research with the aim of developing submissions of cannabis-based products for market authorization as drugs.

Authorization to conduct cannabis-based research is required under the *Cannabis Act*. Authorization for research can be attained by applying for a federal licence from the Cannabis Legalization and Regulation Branch of Health Canada. Sponsors would be required to meet the terms and conditions specified on their licence, including requirements discussed in section 2.2 of this document.

Sponsors seeking to conduct clinical trials with cannabis, using either human or animal subjects, must also receive authorization under the *Food and Drugs Act*. In order to receive authorization, sponsors must file a clinical trial application to Health Canada, or receive an Experimental Study Certificate for certain veterinary research purposes.

The requirements of Division 5 of the *Food and Drug Regulations* ("Drugs for Clinical Trials Involving Human Subjects") continue to apply for all drugs for human use, including those containing cannabis. Information on clinical trial application requirements for drug products can be found in the Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications. Quality (chemistry and manufacturing) requirements for drugs containing cannabis are the same as any pharmaceutical product used in a clinical trial. More information can be found in the Guidance Document — Quality (Chemistry and Manufacturing) Guidance: Clinical Trial Applications (CTAs) for Pharmaceuticals.

In order to conduct veterinary drug research or studies, the current pathways continue to be available for drugs containing cannabis. This includes authorization through an experimental study certificate or by applying for authorization of veterinary investigational new drugs, according to the following forms and guidance:

- Experimental study certificate application form
- HC 3011 Form includes veterinary investigational new drugs

For all research or studies to be conducted using a veterinary drug, the objective is to ensure that there is appropriate oversight to ensure the overall health and welfare and treatment of study animals. If the study includes food-producing animals, Health Canada also considers food safety information.

The requirements of the *Natural Health Products Regulations* apply to clinical trials for Natural Health Products, including those containing permitted parts of the cannabis plant (see section 3.4 for more details on permitted parts). More information about these requirements can be found in the Guidance Document for Clinical Trials.

2.2 Research Licences under the *Cannabis Act*

The *Cannabis Regulations* establish a licence for research that authorizes certain activities in relation to cannabis. This includes, for the purpose of research, possessing, producing and transporting, sending or delivering cannabis between sites that are set out by the licence. In addition, the research licence authorizes the sale of cannabis plants and cannabis plant seeds and the distribution of cannabis, cannabis plants, and cannabis plant seeds to other specific licence holders and persons under the *Cannabis Regulations*. As well, it authorizes the administration and distribution of cannabis to a research subject.

A research licence is granted for a specific research project. In order to obtain a research licence under the *Cannabis Act* and its Regulations, certain requirements will need to be met. The Cannabis Licensing Application Guide sets out the detailed requirements as well as process that should be referred to for more information.

In summary, the requirements to obtain a Research Licence under the *Cannabis Regulations* include the following:

- **Key Individuals, and Licence Holder:** Details on the licence holder as well as the proposed individual responsible person who would bind the licence holder and have overall responsibility for the activities. For example, the licence holder can be an academic institution or research center and the proposed responsible person could be the lead investigator.
- **Site Details:** Details on sites where research and other activities with cannabis are proposed to be conducted.
- **Type of research** that is proposed to be conducted (e.g., in vitro, in vivo (animal), clinical trial, etc.)
- **Research Protocol** outlining the research that is proposed to be conducted, and the quantity of cannabis that is proposed to be possessed or produced must be provided. This must also include the duration for which the research licence is sought (up to 5 years).

- Details describing how **Physical Security Requirements** will be met including how the operations will be designed in a manner that prevents unauthorized access.
- Information demonstrating how any applicable **Record Keeping and Reporting** requirements will be met.

To note that the extent of requirements to be demonstrated for a research licence (in particular around physical security and record keeping) will largely be determined on a case by case basis based on a number of factors including the quantity of cannabis on site and the type and nature of the research, activities and site details.

Depending on the type of activities proposed to be conducted with cannabis and the quantity of cannabis on-site, additional security measures may be required such as security clearances of key personnel. The licence may also be subject to additional conditions such as the need for an organizational security plan or increased physical security measures. Each submission will be assessed on a case-by-case basis.

Once all regulatory and application requirements are met, a research licence may be granted by Health Canada. Once the licence has been issued, licensees must continue to meet all of the regulatory requirements set out in the *Cannabis Act* and its Regulations. Any desired changes to the licence parameters could result in the need to amend a licence, which requires notification and approval of Health Canada in advance of making the change.

3 PRE-MARKET EVALUATION OF HEALTH PRODUCTS UNDER THE FDA

3.1 Context

In Canada, all health products claiming to provide a health benefit, to either humans or animals, must receive market authorization prior to being sold. Health Canada reviews evidence to ensure that the product complies with safety, efficacy, and quality requirements. This pre-market review requirement applies to products containing cannabis, meaning that any health claims for cannabis must receive Health Canada's authorization.

3.2 Prescription Drug Listing & Impacts

Pursuant to the *Food and Drug Regulations*, Health Canada considers several criteria when deciding whether a health product should be sold as a prescription drug. Among these criteria, the Department considers whether the oversight of a practitioner is necessary for Canadians to use the product safely. Substances which are determined to require practitioner oversight are included on the Prescription Drug List (PDL). The factors considered in this process are described in greater detail in Health Canada's Guidance Document: Determining Prescription Status for Human and Veterinary Drugs.

Because of its status as a narcotic under the *Narcotic Control Regulations*, all health products containing cannabis require a prescription from specified classes of practitioners before they could be sold. This limitation does not apply to NHPs and veterinary health products (VHPs) that are marketed with parts of the plant that are excluded from the application of the CDSA (e.g., non-viable hemp seed or hemp seed oil produced in compliance with the *Industrial Hemp Regulations*).

Going forward, the new legislative framework will maintain a similar distinction. Phytocannabinoids will be listed on the Human and Veterinary Prescription Drug List, with limited exceptions that allow permitted parts of the cannabis plant to be included in NHPs and VHPs. These exceptions require the permitted parts of the plant to contain no more than 10 parts per million THC, and no isolated or concentrated phytocannabinoid. Accordingly, any health product containing phytocannabinoids, outside of these exceptions, will require a prescription before it can be sold. Please see sections 3.4 and 3.5 for more details regarding the parts of the cannabis plant permitted in NHPs and VHPs.

The decision to maintain the prescription status of health products that contain phytocannabinoids was based on an assessment of existing prescription drug criteria, such as the need for a practitioner's oversight.

Clinical evidence supporting the safety and efficacy of cannabis and its constituents for therapeutic purposes is growing, but remains limited. While Health Canada has previously authorized health products containing cannabis, there remains significant scientific uncertainty regarding the pharmacological actions and safety of the majority of phytocannabinoids when included in health products. Of the cannabis-based drug products which have been authorized by Health Canada, these have been studied, authorized and used for specific conditions. These authorized products have contributed to the global body of knowledge concerning the safety and efficacy of cannabis-based therapies, but the presence of scientific uncertainty and limited market experience gives rise to the need for a precautionary approach. For more information, please see the notice of intent to amend the Prescription Drug List (PDL).

Health Canada is committed to ensuring that the Prescription Drug List continues to reflect the latest scientific evidence for phytocannabinoids and duplicates of such phytocannabinoids. Until new evidence shows they can be used safely for the intended therapeutic benefit and patient population without a practitioner's oversight, this amendment prevents applications for new non-prescription drugs, natural health products, or veterinary health products that contain phytocannabinoids (other than THC at a maximum of 10 parts per million) or duplicates. Health Canada encourages clinical research in this area and is committed to a fair and evidence-based approach in its oversight of cannabis-based therapies.

To support the development of appropriate regulations to allow for the sale of non-prescription drugs, NHPs, or VHPs containing phytocannabinoids, Health Canada has committed to consult further with Canadians. These consultations will focus on the appropriate level of regulatory oversight and evidence requirements to enable the approval and sale of any potential new health products that could be available without the oversight of a physician. Until these consultations and regulations for these types of products are complete, the *Cannabis Regulations* and the *Food and Drug Regulations* only authorize the sale of a drug containing cannabis to Canadians pursuant to a prescription.

3.3 Prescription Drug Submissions (for human or veterinary use)

Any submission for a new prescription drug containing cannabis will be assessed through the existing drug review process. Consistent with other drug products, sponsors must provide Health Canada with scientific evidence, as defined and required by the *Food and Drug Regulations* (FDR). Health Canada scientists will then review the evidence to determine whether the risks associated with the drug are acceptable in light of its potential benefits. If they are, and if the drug has been

proven to be effective for the proposed indications, Health Canada will authorize the drug for sale in Canada. Upon authorization, a Drug Identification Number and a Notice of Compliance will be issued to the sponsor.

As with any drug submission, the type of safety evidence submitted should take into account the potential risks associated with the product. For example, cannabis contains psychoactive phytocannabinoids such as THC, which could produce physical and psychological dependence and could have the potential to be abused. Therefore, drug submissions containing THC or other phytocannabinoids with psychoactive properties should be accompanied by evidence to support Health Canada in determining whether any potential harms can be appropriately mitigated. The therapeutic benefit of any drug must also be shown to outweigh its potential risk.

Existing guidances and policies related to drug products continue to apply for prescription drugs containing cannabis, including:

Prescription Drugs:

- Guidance for Industry: Management of Drug Submissions
- Guidance Document: Fees for the Review of Drug Submissions and Applications
- Guidance for Industry: Review of Drug Brand Names
- Guidance Document: Product Monograph
- Guidance Document Labelling of Pharmaceutical Drugs for Human Use
- Good Label and Package Practices Guide for Prescription Drugs
- Guidance Document Questions and Answers: Plain Language Labelling Regulations
- Guidance Document: Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)
- Chemical Entity Products/Quality
- Guidance document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document (eCTD)
- Fees in Respect of Human Drugs and Medical Devices
- Data requirements for switching medicinal ingredients from prescription to non-prescription status

Veterinary drugs:

- Guidance for Industry—Management of Regulatory Submissions
- Guidance for Industry—Preparation of Veterinary New Drug submissions
- Guidance for Industry—Preparation of Veterinary Abbreviated New Drug Submissions—Generic Drugs
- Guidance Document: Determining Prescription Status for Human and Veterinary Drugs
- Guidance Document on Cost Recovery—Veterinary Drug Submission Evaluation Fees
- Common Electronic Submissions Gateway
- Guidance Document: Preparation of Regulatory Activities in the "Non-eCTD Electronic-Only" Format
- Annex 4 to the Current Edition of the Good Manufacturing Practices Guidelines —Veterinary Drugs
- Forms—Applications and submissions—Veterinary drugs

3.4 Natural Health Product Applications

The Natural Health Products Regulations (NHPR) have been updated to align with the definition of cannabis in the *Cannabis Act,* and provide greater clarity about the parts of the cannabis plant that can be included in NHPs. Under the updated regulations, which come into effect on October 17, 2018, NHPs can only contain cannabis parts which either do not meet the definition of cannabis in the *Cannabis Act*, or that have been exempted from the *Cannabis Act* through the *Industrial Hemp Regulations (IHR).* These ingredients are:

- Non-viable seeds or roots of the cannabis plant
- Mature cannabis stalks without leaves, flowers, seeds, or branches
- Fibre derived from such a stalk
- Hemp derivatives that are compliant with the IHR.

In addition, the above ingredients must not contain more than 10 parts per million THC, or phytocannabinoids that have been isolated or concentrated. The determination of THC concentration must take into account the potential to convert the acid form into the active form (e.g. delta-9-tetrahydrocannabinolic acid (THCA) into delta-9-tetrahydrocannabinol (THC)).

Any previously approved NHPs (e.g. hemp seed, hemp seed oil, hemp seed protein) would be unaffected by the transition to the new legislative framework, and can continue to be marketed as they are now. Applications for NHPs that contain ingredients compliant with the above requirements would be reviewed under the requirements of the FDA and the NHPR. More information on the requirements to licence, sell or advertise an NHP is available in the following guidance documents:

- Management of Product Licence Applications for Natural Health Products— Attestations
- Pathway for licensing natural health products used as traditional medicines
- Pathway for licensing natural health products making modern health claims
- Guidance Document: Schedule A and Section 3 to the Food and Drugs Act
- Natural Health Products Compliance and Enforcement Policy (POL-0044)
- Guidelines for Consumer Advertising of Health Products

3.5 Veterinary Health Products

Veterinary health products (VHPs) are low risk drugs in final dosage form. They are used to maintain or promote the health and welfare of companion and food-producing animals. They are not for use to treat, prevent or cure disease. VHPs contain ingredients such as: vitamins, minerals, and traditional medicines.

Health Canada regulates VHPs through a Notification Program that was launched in November, 2017. The Program includes VHPs containing hemp derivatives (which are not subject to the *Cannabis Act* pursuant to the *Industrial Hemp Regulations*), and the conditions are outlined in List C: Veterinary Health Products (which is a list incorporated by reference to the *Food and Drug Regulations*). List C is a list of permitted active, homeopathic and traditional medicine substances that are used to make a VHP, and it also includes important conditions.

VHPs may contain cannabis provided they meet the following criteria, as defined under List C: Veterinary Health Products:

- Cannabis sativa (also known as Hemp) when:
  - Derived from the non-viable seed as a dried or as an extract preparation
  - Included in concentrations no greater than 10 ppm of delta 9-tetrahydro-cannabinol (also known as THC) in the product formulation
  - Only for use in Cats, Dogs, Horses not intended for food
  - Only for oral and topical route of administration

Any new VHP containing cannabis that meets the List C parameters would continue to be notified under the Notification Program.

About the VHP Notification Program

3.6 Medical Device Licence Applications

Medical devices cover a wide range of products used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. The scope of medical devices in the context of this guidance document includes:

- medical devices used for the delivery of an associated prescription drug containing cannabis;
- single integrated prescription drug-device combination products;
- medical devices with claims for use in consuming cannabis for medical purposes; and,
- certain test kits that are in-vitro diagnostic devices (IVDDs) used in laboratories for identifying cannabis in patient samples.

A product that is separately sold, manufactured, or represented for use to deliver a unique dosage form of a prescription drug containing cannabis is considered to be a medical device and is subject to the Medical Devices Regulations (MDR). In this case, the device and prescription drug containing cannabis are associated products, in that each product is separately licensed/authorized but specifically labeled for use together, and the respective labeling for each product cross-references the other product. These devices cannot be designed for general application.

A single integrated product that combines a medical device component and a prescription drug containing cannabis component is considered to be a drug-device combination product (DDCP) and is licensed under the *Food & Drug Regulations* (i.e. requires a DIN). According to Health Canada's Policy on Drug/Medical Device Combination Products, a separate device licence is not required in addition to a DIN; however, the safety, quality and effectiveness of the device component must also be demonstrated as part of the overall review process for the DDCP.

A product that is represented for use in consuming cannabis for medical purposes and is intended to be sold separately, such as a vaporizer, is a Class II device under the MDR. Prior to selling such a device in Canada, manufacturers must obtain a Medical Device Licence. Manufacturers of Class II medical devices must attest that they have objective evidence that demonstrate compliance with the safety and effectiveness requirements of the MDR. They also require a Quality Management System Certificate.

The medical devices mentioned above (including the device component in a drug-device combination product that is regulated under the *Food & Drug Regulations*) are considered to be cannabis accessories under the *Cannabis Act*. Please refer to section 5.4 for information on how the *Cannabis Act*'s restrictions on cannabis accessories apply to each of these products.

While certain additional controls apply under the *Cannabis Act*, there are no changes to the licensing requirements that apply to these devices under the MDR. Medical devices that contain cannabis or are for use with cannabis will be subject to the requirements of the *Food and Drugs Act* and the MDR, including applicable requirements for safety, effectiveness and quality. For more information about how medical devices are reviewed in Canada, please see the following guidance documents:

- Safe Medical Devices in Canada
- Guidance Document—Medical devices
- Guidance Document—How to Complete the Application for a New Medical Device Licence
- Guidance Document—Fees for the Review of Medical Device Licence Applications

It should be noted that test kits that are regulated as medical devices under the MDR (e.g., certain in-vitro diagnostic devices that contain cannabis as a reagent or other component) will continue to be examined through the existing review process for medical devices and will also be regulated under the *Cannabis Act* and its regulations. Information about the authorizations provided for these products under the *Cannabis Act* is available in section 5.4.

3.7 Management of enquiries, submissions and applications

In an effort to provide stakeholders with consistent information on the current regulatory requirements, the Health Products and Food Branch of Health Canada has created a single window for questions related to health products with cannabis. This single window will manage and respond to all enquiries associated with the development of submissions and applications for health products containing cannabis, or for use with cannabis, including human drugs, natural health products, medical devices as well as clinical trials. Enquiries related to veterinary products will continue to be handled by the Veterinary Drugs Directorate.

Requests for pre-submission meetings should also be directed to the single window.

Health Canada will manage submissions and applications for health products containing or for use with cannabis through the usual processes.

- For human prescription and non-prescription drugs as well as medical devices, please consult Guidance for Industry: Management of Drug Submissions.
- For natural health products, please consult Management of Product Licence Applications for Natural Health Products
- For veterinary drugs (prescription and non-prescription), please consult Guidance For Industry Management of Regulatory Submissions

4 CANNABIS DRUG LICENCE

4.1 Context

Prior to the coming into force of the *Cannabis Act*, the manufacturing and production of prescription drugs containing cannabis is subject to licensing requirements under the FDA and the CDSA. A Drug Establishment Licence (DEL) is required under the FDR for any person to fabricate, package/label, import, perform tests on, distribute or wholesale authorized drugs. In addition to a DEL, a Dealer's Licence is required under the NCR for any person to conduct activities such as to produce, make, assemble, sell, provide, transport, send or deliver a narcotics, such as cannabis, which is used as an ingredient in those drugs.

Under the *Cannabis Regulations*, a DEL will still be required and any Dealer's Licence that authorized the possession, sale or distribution of drugs containing cannabis will be transitioned to a Cannabis Drug Licence (CDL). The following sections provide more detail about the requirements for holding a CDL, as well as the activities that it can authorize. In general, the regulations authorize a CDL holder to possess cannabis and to produce, distribute and sell a drug that contains cannabis so long as those activities align with the activities authorized in their DEL.

4.2 Cannabis Drug Licence Requirements

In general, CDL holders must comply with the record keeping, reporting, and security requirements set out in the *Cannabis Regulations*, as well as any applicable provisions in the *Food and Drug Regulations*.

CDL holders must have processes in place for recording transactions relating to licensed activities, including maintaining appropriate records of transactions with both suppliers and clients. The record-keeping system must also allow for the reconciliation of orders for drugs containing cannabis and shipments and inventories of drugs containing cannabis.

Original documents must also be maintained in order to provide the necessary reports to the Minister[1] and licensing authorities, and to respond to requests for information from the Minister as required.

[1] Throughout this guide, there are references to actions that would be taken by the Minister of Health under the *Cannabis Act* and its Regulations, often in the context of decision-making. In many cases, it is anticipated that the decision-making function would not be exercised personally by the Minister, but instead by an official in the Department of Health who is in a capacity appropriate to making the decision. This would be consistent with ministerial decision-making practices in many other contexts, and in accordance with the common law and the *Interpretation Act*.

For physical security requirements, CDL applicants have the option of choosing to comply with one of two systems. They can comply with the Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis (the Security Directive) as referenced in Part 8 of the *Cannabis Regulations*, or they can choose to comply with the security requirements under Part 4 of the *Cannabis Regulations*. The Security Directive has different requirements based on the amount of cannabis and controlled substances being stored at the site and can require secure vaults for larger amounts. The requirements under Part 4 of the *Cannabis Regulations* are focused on ensuring a secure perimeter and controlling access to key areas at licensed sites, and vary according to the amount of cannabis sold or distributed to them. For more information regarding the security requirements please see the Cannabis Licensing Application Guide.

Under Part 8 of the *Cannabis Regulations*, the holder of a CDL must also retain the services of certain key individuals with responsibility for the management of licensed activities or the supervision of authorized activities. This includes a Senior Person in Charge, a Qualified Person in Charge, and the option of having Alternates for the Qualified Person in Charge. CDL applicants must provide a criminal record check for these individuals as part of their application, to ensure they are compliant with the eligibility requirements of the regulations.

For more information on how to apply for a CDL, please see Annex A.

4.3 Authorizations for Sale

CDL holders are authorized to sell drugs containing cannabis to organizations and individuals listed in the *Cannabis Regulations*, including:

- Cannabis Drug Licence holders
- Pharmacists
- Practitioners (e.g., physicians, veterinarians)
- Hospital employees (e.g., individual in charge of a hospital)
- Researchers
- Analytical Testers
- Licensed Dealers or another holder of a licence issued under the *Cannabis Regulations* for the purposes of destruction

It should also be noted that CDL holders cannot sell a drug containing cannabis to pharmacists or practitioners who are named in a notice, as described in section 6 of this document.

5 *CANNABIS ACT* RESTRICTIONS AND AUTHORIZATIONS THAT APPLY TO HEALTH PRODUCTS

5.1 Context

The definition of cannabis in the *Cannabis Act* includes any part of the cannabis plant, with a few exceptions, as well as the phytocannabinoids found in or produced by the plant, regardless of how they are obtained. The parts of the plant that fall outside of this definition are identified in Schedule 2 of the Act and generally do not contain phytocannabinoids in significant levels (i.e., non-viable seeds; mature stalks without any leaf, flower, seed or branch; fibre derived from such a stalk; or the roots). This broad definition means that any health product containing cannabis, including phytocannabinoids, is subject to the *Cannabis Act*, and that all of its prohibitions apply unless regulatory authorizations or exemptions are sought to enable certain activities.

5.2 Prescription Drugs (for human or veterinary use)

Access to prescription drugs is subject to a number of controls under the *Food and Drug Regulations*. In general, only provincially authorized practitioners can provide prescriptions for these drugs, and they can only be dispensed by a provincially licenced pharmacist. The oversight of these healthcare professionals helps to limit Canadians' access to prescription drugs, and ensures their use is subject to necessary medical advice and care.

Given the well-established access controls already in place for prescription drugs, a number of prohibitions under the *Cannabis Act* would be duplicative or unnecessarily limit practitioners' ability to care for their patients. As such, the *Cannabis Regulations* provide the necessary authorizations and exemptions to subject prescription drugs containing cannabis to similar controls to the existing ones. This includes authorizing:

- the sale of any dosage form authorized by Health Canada as safe and effective (i.e., prescription drugs are not limited to the permitted classes for sale listed in Schedule 4 of the *Cannabis Act*, and may include substances prohibited in Schedule 5);
- the possession of prescription drugs in accordance with a prescription for personal use without affecting public possession limits (i.e., an adult may possess prescription drugs for personal use in addition to the 30g of dried cannabis, or its equivalent, that they are permitted to possess in public);

- the use of an illustration that depicts an animal on the package or label of a drug for veterinary use, so long as the animal depicted is the same as the animal for which the drug is intended; and,
- pediatric formulations of prescription drugs to be presented in a way that helps administer the product to children for therapeutic purposes (e.g., flavour).

The *Cannabis Regulations* also authorize drug manufacturers to promote prescription drugs containing cannabis in the same way as any other approved prescription drug, including authorizing:

- the promotion of prescription drugs by communication of their name, price and quantity, subject to advertising restrictions of the *Food and Drugs Act*; and,
- the use of prescription drug brand names, as well as the name of DIN holders, in sponsoring promotional events or in the name of a cultural or sports facility.

The packaging and labelling of prescription drugs containing cannabis will be controlled under the existing requirements of the *Food and Drug Regulations*. Therefore, prescription drugs will not be subject to the packaging and labelling requirements of the *Cannabis Regulations* that apply to cannabis products. However, the packaging and labelling prohibitions at the level of the *Cannabis Act* (e.g., cannot appeal to young persons, use testimonials, depict a person, or use lifestyle advertising) continue to apply to prescription drugs, unless otherwise authorized.

5.3 Natural Health Products and Veterinary Health Products

Natural health products and veterinary health products are only permitted to include parts of the cannabis plant that are not subject to the *Cannabis Act* (i.e., parts of the cannabis plant listed on Schedule 2, or cannabis derivatives produced in accordance with the *Industrial Hemp Regulations* that do not contain isolated or concentrated phytocannabinoids or synthetic duplicates of such phytocannabinoids), therefore these products are not subject to any of the *Cannabis Act*'s restrictions or prohibitions. Health Canada may request a Certificate of Analysis to identify the levels of phytocannabinoids in the above-mentioned parts.

5.4 Medical Devices

As indicated in section 3.6, medical devices containing cannabis or for use with cannabis are subject to the requirements of the *Food and Drugs Act* and the *Medical Devices Regulations*. In addition, these devices fall under the definition of a cannabis accessory in the *Cannabis Act*. Accordingly, they are subject to the *Cannabis Act*, and would be subject to its prohibitions without regulatory authorizations or exemptions. To ensure that only appropriate controls apply to these devices, the regulations provide the necessary authorizations and exemptions.

The *Cannabis Regulations* authorize, pursuant to a prescription, the sale to a young person of a medical device that delivers, or is in combination with, a prescription drug containing cannabis. The Regulations also include authorizations and exemptions for combination products that are authorized as drugs to be promoted in the same way as approved prescription drugs, including authorizing:

- their promotion by communication of their name, price and quantity, subject to advertising restrictions of the *Food and Drugs Act; and,*
- the use of their brand names, as well as the name of DIN holders, in sponsoring promotional events or in the name of a cultural or sports facility.

Devices with claims for use in consuming cannabis for medical purposes are fully subject to the prohibitions and requirements that apply to cannabis accessories under the *Cannabis Act* and associated Regulations. This includes restrictions on the sale and display to young persons, as well as restrictions on product traits or attributes that appeal to youth. However, a young person who has received a medical document from their doctor will still be able to purchase a cannabis accessory (including a licensed medical device) from a holder of a licence for sale under the *Cannabis Regulations*.

Test kits that are regulated as medical devices under the MDR (i.e., in-vitro diagnostic devices that contain cannabis as a reagent or other component) are also regulated under the *Cannabis Act*. The *Cannabis Regulations* provide a number of authorizations and exemptions from the *Cannabis Act* to allow for activities such as sale, importation, possession and distribution of test kits containing cannabis and includes requirements for their registration, similar to the previous requirements under the CDSA. Any applications for new test kits containing cannabis would continue to be examined through the existing review process for medical devices under the MDR, and also be reviewed as test kits under the *Cannabis Regulations*.

6 PRACTITIONERS, PHARMACISTS AND HOSPITALS

6.1 Context

Under the current legal framework for controlled substances, including cannabis, the NCR authorize a specific set of practitioners to perform activities with drugs containing controlled substances, and also impose certain obligations in relation to these activities.

Upon their coming into force, the *Cannabis Regulations* will authorize practitioners (human and veterinary) to prescribe approved drugs containing cannabis so long as they are entitled by their respective province or territory to treat patients with prescription drugs. This is consistent with the approach for other approved prescription drugs.

As it relates to prescription drugs, the *Cannabis Regulations* largely mirror the NCR framework that previously applied to cannabis in respect of possession, sale and distribution, record keeping and reporting. As this document is only intended to summarize the main points of the content of the new *Cannabis Regulations*, please refer to the Regulations in their entirety.

6.2 Authorizations

Pharmacists

Pharmacists will be authorized to possess drugs containing cannabis as prescribed in the *Cannabis Regulations*, and will be authorized to sell, distribute and administer those drugs to a person who:

- is exempt from the prohibition on possession; or
- has a written order or prescription from a practitioner.

To address the needs of an emergency situation, the Regulations also authorize the sale of a prescription drug containing cannabis from one pharmacist to another.

Practitioners

A practitioner is authorized to administer a drug containing cannabis to an individual or an animal, or to sell or distribute such a drug for an individual or animal in their care if the drug is required for the condition for which they are receiving treatment.

Hospitals

In general, the authorization of the individual in charge of a hospital is required before a prescription drug containing cannabis can be sold, distributed or administered by the hospital. These activities must also be in accordance with a prescription or written order.

To address the needs of an emergency situation, the Regulations also authorize, with some prescribed conditions, the sale or distribution of a prescription drug containing cannabis to an employee, practitioner or pharmacist in another hospital.

6.3 Obligations

The *Cannabis Regulations* set out record keeping requirements that ensure any transactions with drugs containing cannabis are documented. When drugs are sold to patients pursuant to a prescription, or between professionals pursuant to a written order, whether it is for return, destruction, or in an emergency situation, details about the drug must be recorded. Records are to be maintained for a period of at least two years.

6.4 Notices

Additional controls are required to regulate the sale and distribution of health products containing cannabis to health professionals who have been sanctioned by their provincial or territorial college or where Health Canada has become aware of other compliance issues. The *Cannabis Regulations* set out the circumstances where the Minister must issue a notice stating that drugs containing cannabis must not be sold or distributed to the pharmacist or practitioner named in a notice. The notices also serve to prevent prescriptions or orders for drugs containing cannabis issued by that practitioner from being filled. These circumstances are:

a. the pharmacist or practitioner named in the notice made a request to the Minister to issue the notice;

b. the pharmacist or practitioner contravened a rule of conduct, in relation to cannabis, established by the provincial professional licensing authority, and that licensing authority has requested the Minister to issue the notice;

c. the pharmacist or practitioner is convicted of an offence set out in the *Cannabis Regulations*; *or*

d. the Minister has reasonable grounds to believe that the pharmacist or practitioner contravened the applicable parts of the regulations.

The Minister also has the discretion to issue a notice if a number of other circumstances exist. Notices are issued to the pharmacist or practitioner named in the notice, all CDL holders, all pharmacies and applicable provincial professional licensing authorities in the province where the pharmacists or practitioner is entitled to practice, and any applicable provincial professional licensing authority in any other province if they request a copy. When a practitioner is named in a notice, all pharmacies in an adjacent province will also receive the notice.

6.5 Other

Security Obligations

Practitioners, pharmacists and individuals in charge of a hospital are required to protect drugs containing cannabis against loss or theft and notify Health Canada if they become aware of a loss or theft within 10 days of becoming aware.

Return and Destruction

In addition to the general authorizations set out in the Regulations will allow practitioners, pharmacists, and hospitals to sell and distribute drugs containing cannabis, those individuals will also be authorized to sell and distribute drugs containing cannabis to the following federal licence holders for the purpose of inventory returns or for the destruction of those drugs:

a. The holder of a CDL from which they received the drug for inventory returns; and,

b. A holder of a dealer's licence under the NCR or a holder of a CDL for destruction.

For post-consumer returns, pharmacists may also sell or distribute a prescription drug containing cannabis to a holder of a dealer's licence under the NCR who specializes in destruction.

Rules related to handling and destruction of unserviceable stock and post-consumer returns for controlled substances that exist by virtue of the section 56 exemption under the CDSA, will continue to apply for cannabis. The following guidance document can be relied upon to clarify the recommended procedures for the collection, handling, and destruction of post-consumer returns and unserviceable stock of cannabis.

Guidance Document: Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances

Guidance Document: Handling and Destruction of Post-consumer Returns Containing Narcotics, Controlled Drugs or Targeted Substances

7 ADDITIONAL REQUIREMENTS

7.1 Import and Export

Under the *Cannabis Regulations*, a holder of a licence is authorized to import or export cannabis for medical or scientific purposes if they also hold an import or export permit. Cannabis Drug Licence holders seeking to import or export cannabis to be used as an ingredient in health products, or health products containing cannabis in final dosage format, are subject to the requirement to obtain an import or export permit from Health Canada for those activities. This is required for each shipment of cannabis that is imported or exported.

The import and export of drugs containing cannabis, or of cannabis to be used as an Active Pharmaceutical Ingredient, must also comply with the requirements of the *Food and Drugs Act* (e.g., Drug Establishment Licence).

The holder of an import or export permit is also authorized to possess, transfer, transport, send, or deliver, or in the case of export, sell, the shipment of cannabis to the extent necessary for the import or export. The permit is issued by the Minister of Health, and has a specific validity period.
Refer to www.canada.ca/cannabis for further information.

It is important to note that there is no provision to allow a traveller to import/export cannabis on their person. This can only be authorized through a section 140 exemption under the *Cannabis Act*, or a section 56 exemption under the *Controlled Drugs and Substances Act* that continues to apply under the transitional provisions of the *Cannabis Act*.

The Section 56 Class Exemption For Travelers Who Are Importing or Exporting Prescription Drug Products Containing a Narcotic or a Controlled Drug authorizes the personal import and export of prescription drugs containing cannabis (such as Sativex) under certain conditions, and continues to apply. This exemption has no stated expiration date, so it remains in force until it is revoked or amended.

8 ANNEX A: CANNABIS DRUG LICENCE APPLICATION DETAILS

In order to obtain a CDL under the *Cannabis Act* and its Regulations, certain requirements must be met. *The Cannabis Act* establishes that an application for a licence must be filed with Health Canada in the form and manner specified by the Minister of Health and set out the information required by the Minister.

In general, CDL holders must comply with the record keeping, reporting, and physical and personnel security requirements of the Regulations.

A summary of key requirements that must be met in order to obtain a CDL include:

- Having a valid **Establishment License** (DEL) authorized under the FDA for specific activities:
  - For possession of cannabis under the *Cannabis Act*, a DEL for fabricating, packaging/labelling, distributing, importing, wholesaling or testing a drug containing cannabis
  - For production of a drug containing cannabis under the Cannabis Act, a DEL for fabricating the drug, or
  - For sale of a drug containing cannabis under the *Cannabis Act*, a DEL for packaging/labeling, distributing, importing or wholesaling the drug
- The addresses of the buildings in the EL must be the same as the building for the CDL application
- **Key Individuals:** Details on the licence holder. In addition, the following must be identified:
  - **Senior Person in Charge:** An applicant for a cannabis drug licence must retain the services of an individual as the senior person in charge who has overall responsibility for management of the activities with respect to cannabis that are specified in the licence application. The Senior Person in Charge is considered the representative of the applicant. This individual is the official point of contact for Health Canada.

- **Qualified Person in Charge:** An applicant for a cannabis drug licence must retain the services of an individual as the qualified person in charge who is responsible for supervising the activities with respect to cannabis that are specified in the licence application and for ensuring, on behalf of the applicant, that those activities comply with these Regulations. To assess the qualifications of the proposed Qualified Person in Charge, the applicant must submit information as to how the qualified Person in Charge meets the requirements (knowledge/experience, familiarity with the Act and Regulations, appropriate diplomas/degree). A qualified alternate may be identified. This alternate must be identified in advance and requires approval by Health Canada because there are specific qualifications for this position.
- For both of these individuals, a document issued by a **Canadian police force** in relation to them is required indicating whether, during the 10 years before the day on which the application is submitted, the person was convicted of an offence as specified in section 151 in the *Cannabis Regulations*, such as a designated offence under the *Cannabis Act* or an offence involving a criminal organization under the *Criminal Code*.

- **Site Details:** This includes the site address, a site survey, an aerial view, and specific details on the buildings and rooms. The proposed site address must be the same as the address under which the applicable establishment licence has been issued. In addition, each building must be included on the DEL for the corresponding activities. As well, site ownership information is required if the applicant is not the owner of the site.
- Details describing how **Physical Security Requirements** will be met. For physical security requirements, CDL applicants have the option of choosing to comply with one of two systems. They can comply with the *Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis* (the Security Directive) referenced in Part 8 of the *Cannabis Regulations*, or they can choose to comply with the security requirements for holding a licence for processing under the *Cannabis Regulations*. The Security Directive has different requirements based on the amount of cannabis being stored at the site and can require secure vaults for larger amounts. The requirements for a processing licence are focused on ensuring a secure perimeter and controlling access to operations and storage areas and vary according to the amount of cannabis sold or distributed to them. For more information, see the Security Directive.
- Information demonstrating how any **Record Keeping and Reporting** requirements will be met.

Anyone wishing to submit an application should contact Health Canada by email (information available in Appendix B). Health Canada will work closely with the applicant to outline the requirements and the process for submitting the CDL application.

Once all licence application requirements are met, a CDL is granted by Health Canada. Licensees must meet all of the relevant regulatory requirements set out in the *Cannabis Act* and its Regulations. Any desired changes to the licence parameters could result in the need to amend a licence, which requires notification and approval in advance of making the change. The Regulations and additional Health Canada guidance should be referred to for more information.

For more information on other classes of licences under the *Cannabis Act and* its Regulations, applicants may refer to the Cannabis Licensing Application Guide which sets out requirements for many of the licence classes and subclasses under the *Cannabis Regulations*, and how they must be submitted through the **Cannabis Tracking and Licensing System (CTLS).**

9 ANNEX B: WHERE TO REQUEST FURTHER INFORMATION

For information to support the development of an application for a drug for human use, a natural health product, or a medical device, the cannabis single window can be reached at: hc.hpfb_cannabis_dgpsa.sc@canada.ca

For information about veterinary drugs and veterinary drugs, the Veterinary Drugs Directorate can be reached at: hc.vetdrugs-medsvet.sc@canada.ca.

For information about veterinary health products, please contact: hc.VHP-PSA.sc@canada.ca

To apply for a Cannabis Drug Licence, please contact Health Canada at: cannabis@canada.ca. The Department will work closely with applicants to outline the requirements and the process for submitting an application.