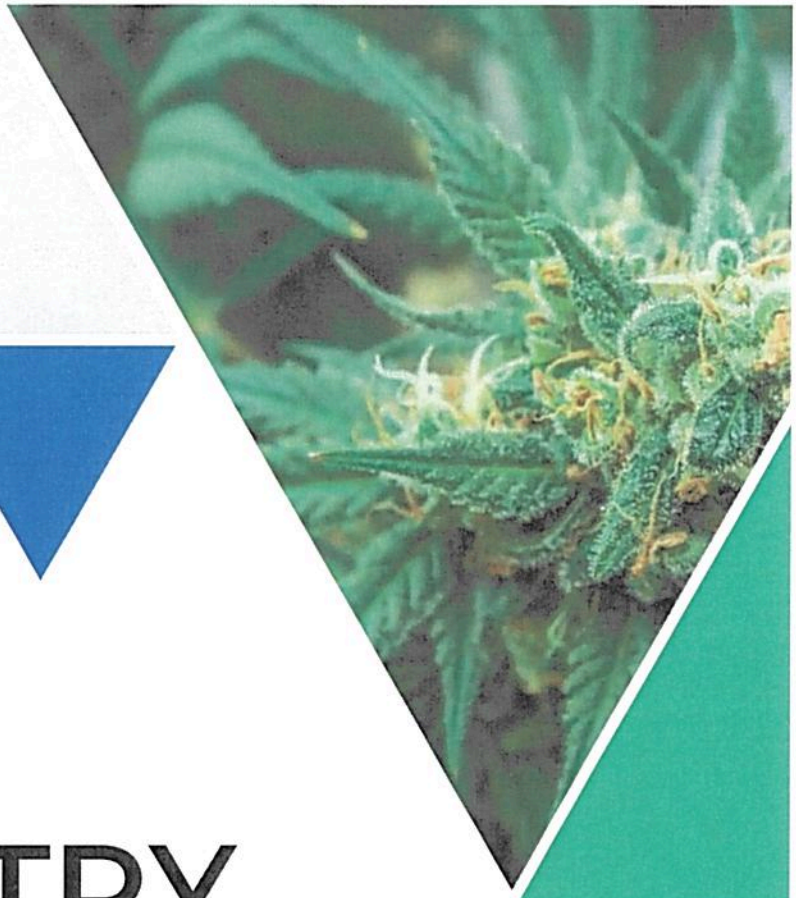

INDUSTRY STANDARDS

Packaging & Labelling of medicinal cannabis products - Specification

PREPARED BY

Barbados National Standards Institution (BNSI)

Foreword

This Industry Standard SP 2: 2021 has been prepared and issued by the Barbados National Standards Institution. It was approved for publication 28th October, 2021. This Standard was developed at the request of the Barbados Medicinal Cannabis Licensing Authority (BMCLA) for the cannabis industry under an Agreement.

The supplementary information contained is intended to inform the customer, authorized patient or caregiver of essential characteristics to improving the authorized patient's ability to make a critical and better-informed decision.

All cultivators, manufacturers, importers, retail distributors and other entities engaged in the production and or trade of cannabis and cannabis containing products for medicinal purposes within the Member State of Barbados shall comply with the requirements of this standard. The following documents have been used in the development of this standard:

a) Barbados National Standard Specification for Labelling of Prepackaged Foods – BNS 5 : Part 2: 2004

b) Standard Guide for Packaging and labeling of Consumer Resin Cannabis Products for Sale to Adult Consumers, Legally Authorized Medical Users, and Caregivers in a Business-to-Consumer Retail Environment (Retailers) – D8233 -19 – ASTM International

c) Packaging and labelling guide for cannabis products – Requirements under the Cannabis Act and the Cannabis Regulations – Health Canada – August 30, 2019

This document is an Industry Standard and in no way shall be referred to as a Barbados National Standard.

Highlight elements within this document such as coloured text and highlighted text background are intended to draw the users to attention to critical matters where the Committee believes conformance to the requirements were absolutely essential to address safety of persons.

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Contents

Packaging and labelling of medicinal cannabis products — Specification

1 Scope

1.1 This standard applies to the packaging and labelling of harvested cannabis for further processing for medicinal purposes, and medicinal cannabis and cannabiniod products parcelled in individual packages and cartons intended to be offered to the consumer for medicinal purposes or for retail sale in Barbados.

1.2 It is applicable to the packaging and labelling of all medicinal cannabis and cannabis products inclusive of non-consumer facing transactions (for example, products packaged for transfer between business entities, inclusive of growers, processors, manufacturers, wholesalers and retailers), irrespective of sizes.

1.3 This standard specifies the requirements for the packaging, the information and method of display of such information, the wording and presentation of health warnings to be included on the labels of retail packages.

1.4 The Medicinal Cannabis Industry Regulations, 2020 requires all applicants, licensees and registrants who package cannabis products for ultimate sale to a consumer, patient, or designated primary caregiver to have packages and labels approved through the Barbados Medicinal Cannabis Licensing Authority pre-approval.

1.5 "Ultimate sale" means the final sale by authorized personnel from a retail location or dispensary to a consumer, patient, or designated primary caregiver. Packages and labels shall be approved before any cannabis product is sold, offered for sale, or transferred between licensees or to a consumer, patient, or caregiver, unless subject to an exception. This standard is not applicable to products:

a) products containing a cannabinoid concentration less than or equal to;

b) edibles and other forms of recreational cannabis products;

c) intended for export only, which complies with the requirements of standards or laws on labelling of the country to which they are being exported; and

d) cosmetic products used for body care functions.

EXAMPLE Shaving cream, hair shampoos.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

a) Medicinal Cannabis Industry Regulations, 2020;

b) Barbados Medicinal Cannabis Industry Act, 2019-44;

c) Health Services Act, Cap 44;

d) Drug Abuse (Prevention and Control) Act. Cap 131;

e) Therapeutic Substances Regulations, 1950/173, (Made by the Minister under section 18 of the Therapeutic Substances Act. Cap 330); and

f) ISO 8317:2015 – Child-resistant packaging – Requirements and testing procedures for reclosable packages.

3 Terms and definitions

For the purposes of this standard, the following terms and definitions shall apply:

3.1
active ingredient
each of the following ingredients in a medicinal cannabis product:

a) delta-9-tetrahydrocannabinol and its corresponding acid;

b) cannabidiol and its corresponding acid;

any other bioactive ingredient that is derived from cannabis or an additive

3.2
address
identifiable or registered place of the business of:

a) the cultivator, producer, manufacturer or packager of the medicinal cannabis product; or

b) the entity for whom the products are manufactured , retailed or packaged; or

c) the importer and retailer or distributor of the products.

3.3
applicant
person or entity who is in the process of applying to be a licensee or registrant under the Medicinal Cannabis Act (2019-44)

NOTE Applicants cannot receive package or label approval until they become a licensee or registrant.

3.4
analytical services
services for the testing or abstraction of cannabis and related products

3.5
authorised personnel

(a) a pharmacist;

(b) a graduate pharmacist, under the supervision of a pharmacist; or

(c) an intern who is studying to be a pharmacist, under the supervision of a pharmacist

3.6
batch
production-scale quantity of any cannabis-based ingredient or medicinal cannabis product that

a) is made during a single cycle of manufacture;

b) has a uniform composition, method of manufacture, traceability and probability of chemical or microbial contamination;

c) is traceable to a licensed producer

3.7
cannabis
any plant of the genus *Cannabis* from which the resin has not been separated and includes any part of the plant by whatever name it be designated

NOTE Hemp Strains will not be considered.

3.8
cannabis-based ingredient
ingredient that is extracted from cannabis and is intended to be used in, or for, a medicinal cannabis product

3.9
cannabis material

a) cannabis;

b) cannabis resin;

c) any other raw or processed material derived from cannabis

NOTE Hemp Strains will not be considered.

3.10
cannabis resin
separated resin, whether crude or purified, obtained from any plant of the genus *Cannabis*

3.11
cannabidiol
<CBD>
active ingredient found in the cannabis plant which reacts with specific receptors in the human body to give a therapeutic or biological effect

3.12
carton
any collective unit of packages of medicinal cannabis products which is designed to be displayed and or sold in the retail trade as per the legislation

NOTE Carton packages of cannabis or related products shall be traceable to the licensed producer and are expected to meet the requirements outlined for exit packages or 'outermost containers.

3.13
cartoon
any drawing or depiction of an object, person, animal, creature or any similar caricature that:

a) Uses comically-exaggerated features;

b) Attributes human characteristics to animals, plants or other objects; or

c) Attributes unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunnelling at very high speeds, or transformation (i.e., Super heroes).

3.14

case
shipping container designed for the transportation and storage of packages or cartons of medicinal cannabis products and which is intended for use in the wholesale trade

3.15
child-resistant packaging
packaging that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly

3.16
claim
any validated representation which states, suggests or implies that a product has particular qualities relating to its origin, active properties, nature, processing, composition or any other quality

3.17
comparative claim
claim that compares the potency levels and or action of two or more products

EXAMPLE "reduced", "less than", "fewer", "more than".

3.18
competent authority
ministry, department or agency of government administering any law regulating the labelling of medicinal cannabis and cannabis containing products

Note 1 to entry: The BMCLA as outlined in Section 4 of the Barbados Medicinal Cannabis Industry Act 2019.

3.19
consumer
authorized persons/patients purchasing and receiving medicinal cannabis product, in order to meet their medicinal needs as prescribed by physician

3.20
container
defined as a sealed, hard or soft-bodied non- transparent or opaque receptacle with a safety cap, or other form of closure, which is child resistant in which a cannabis product is placed and any outer receptacle intended to display a medicinal cannabis product for ultimate sale to a consumer. This definition refers to any package or receptacle that holds a medicinal cannabis product and all outer packages used to display the medicinal cannabis product

NOTE 1 A container may enclose several units packages and shall be traceable along with its contents.

NOTE 2 If a licensee packages an extract in a small round jar and then puts that jar into a cardboard box, both the jar and the box will be considered containers.

3.21
contaminant
any substance not intentionally added to the product, which is present in such a product as a result of the production (including operations carried out in crop rearing), manufacture, processing, preparation, treatment, packing, packaging transport or holding of such products, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter

3.22
country of origin

a) country where the raw cannabis material was sourced and processed and the medicinal cannabis product wholly manufactured;

b) when a product undergoes processing in a second country which changes its nature, both the

country in which the cannabis was produced and the country of processing shall be declared for the purposes of labelling and tracing of the cannabis material.

3.23
date of manufacture
date on which the medicinal cannabis product becomes the final product as described

3.24
date of harvest
date the mature cannabis plants in a harvest lot were removed from the soil or other growing media. If the harvest occurred on more than one day, the "date of harvest" is the day the last mature cannabis plant in the harvest lot was removed from the soil or other growing media

3.25
date of minimum durability
<best before>
date which signifies the end of the period under any stated conditions which the product will remain fully marketable and will retain any specific qualities for which tacit or express claims have been made. However, beyond that date the product may still be perfectly satisfactory

3.26
expiration date
date which signifies the end of the estimated period under any stated storage conditions, after which the product probably will not have the quality attributes normally expected by the patient and the healthcare provider.

NOTE After this date, the product should not be regarded as marketable or usable as per national regulations.

3.27
graphic
any symbol, sign, logo, mark, trademark, pictures, images, pattern, emblem, design, recognizable colours or patterns of colours or any other indicia

3.28
health warning
written and graphic messages that appear on the packaging of medicinal cannabis products in an effort to enhance the public's awareness of the effects of the use of medicinal cannabis products

NOTE Health warnings are placed in the warning area.

3.29
harvest
process of gathering every plant that is reaped, whether manually or by way of machinery, whether or not that plant is dead or deemed to have no commercial value or viability

3.30
health claim
validated representation which states, that a relationship exists between a product, or a constituent of that product, and health

3.31
ingredient
substance, including a food additive, used in the manufacture or preparation of a product and present in the final medicinal cannabis product although possibly in a modified form

3.32
international non-proprietary name
<INN>
official generic and non-proprietary name which identifies a pharmaceutical substance or active

ingredient and is unique, globally recognized and is public property.

3.33
label
brand, mark, pictorial or other descriptive matter written, printed, or graphically affixed to, applied to, attached to, blown into, formed, moulded into, embossed on, printed on, or appearing upon a package containing a medicinal cannabis product for purposes of branding, identifying, or giving any information with respect to the item or to the contents of the package as produced by the manufacturer.

3.34
labelling
written, printed or graphic matter that is present on the label

3.35
licence
authorization issued by the Competent National Authority to facilitate the production and handling of medicinal cannabis pursuant to the Medicinal Cannabis Industry Act, 2019

3.36
licensee
any person or entity who holds a license issued by the Barbados Medicinal Cannabis Licensing Authority under the categories outlined in the Third Schedule of the regulations

3.37
limit quantification
<LOQ>
the lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met. The LOQ may be equivalent to the limit of detection or it could be at a much higher concentration

3.38
lot
definitive quantity of a medicinal cannabis product produced essentially under the same conditions and traceable to a batch

3.39
principal display panel "PDP" (main panel/front label where possible)
part of the package label which is most likely to be displayed, shown or examined under customary conditions of use or display for retail sale

3.40
manufacturer
commercial entity that legally processes, prepares, or packages any medicinal cannabis or cannabinoid product for sale

3.41
Medical grade symbol
image established by the BMCLA and made available to licensees indicating the cannabinoid product, concentrate or extract may only be sold or transferred to a designated primary caregiver or patient, for use only by a patient

3.42
package
bottle, box, pouch, bag, tube or other container in which medicinal cannabis or cannabinoid products are sold, except for cartons and cases

NOTE The package shall be opaque and carries a safety cap, or form of closure which is child resistant and has a tamper proof component.

3.43
retail sale
commercial supply of medicinal cannabis products by a licensed retailer directly to the patient or caregiver

3.44
pre-packaged
packaged or made up in advance in a container, ready for offer to the patient or caregiver, or for manufacturing purposes

3.45
processing aid
materials, excluding solvents, used to aid in the manufacture of an excipient, intermediate, or Active Pharmaceutical Ingredient (API) that do not themselves participate in a chemical or biological reaction

3.46
registrant
person or entity registered with the Barbados Medicinal Cannabis Licensing Authority under the Medicinal Cannabis Industry Regulation 2020

3.47
resealable
immediate container which maintains its child-resistant effectiveness for multiple openings

3.48
security shipping container
lockable, hard-sided container with a lid or other enclosure that can be secured in place for purposes of transporting cannabis products to and from licensed cannabis businesses, including licensed, cultivators, processors, retail distributors and research and testing facilities

NOTE Containers shall be inspected by the BCMLA.

3.49
tamper proof
seal or closure of a package designed to reveal any prior interference with the contents

3.50
therapeutic
intended to prevent, diagnose, monitor, alleviate, treat, cure, or provide symptomatic treatment for a disease, ailment, or injury in a person

3.51
delta-9-tetrahydrocannabinol
<THC>
main active ingredient in cannabis and one of the many naturally occurring chemical compounds found in cannabis

3.52
delta-9-tetrahydrocannabinolic acid
<THCA>
precursor of tetrahydrocannabinol, an active component of cannabis

3.53
track and trace system
system used by the authority to monitor a cannabis business and the movement of cannabis from the cultivation of the seeds to the final sale of the cannabis or medicinal cannabis product

3.54
Unique Identification Number

<UID number>
for the purpose of labelling, means the unique identification number generated by Cannabis Tracking System at the time the cannabis product was packaged and labelled for ultimate sale to a health care provider, patient, or designated primary caregiver

3.55
universal symbol
image, established by the Authority and made available to licensees and registrants, indicating the medicinal product contains cannabis.

3.56
warning area
surface area of the package label of medicinal cannabis products on which the health warning is to be placed

4 General principles

4.1 Packaged medicinal cannabis products shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

4.2 Packaged medicinal cannabis products shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive, either directly or indirectly, of any other product with which such product might be confused, or in such a manner as to lead the patient and the healthcare provider to suppose that the product is connected with such other product.

4.3 Where the cannabis from a cultivation site is to be packaged for retail sale it shall be packaged in accordance with the requirements of this standard, as applicable.

4.4 Packaged medicinal cannabis products shall not be presented in a form that is attractive to children or that will promote the misuse of the product.

4.5 With the exclusive exception of the declared major use or purpose of the medicinal cannabis product all claims made for cannabis products, inclusive of comparative claims shall be prohibited.

4.6 All cultivators, manufacturers, importers, retail distributors and other authorized entities shall comply with the requirements of this standard. Every package and or carton of medicinal cannabis products intended for retail sale shall bear labels which shall carry, in legible form, the following information in the English language:

NOTE Medicinal cannabis products for export shall satisfy the regulatory requirements of the importing country.

4.7 All Medicinal Cannabis products inclusive of medical cartridges and vaporizing devices containing a cannabinoid concentrate, extract or product intended for use with an inhalant or sublingual delivery system are required to be labelled in accordance with this specification except that the cartridge or device shall have a label displaying the universal symbol, as appropriate. All other label requirements shall be included on the packaging for compliance.

4.8 The competent national authority shall require that medicinal cannabis products retailed and sold by licensees be labelled with a Universal Product Code.

4.9 Once a label is approved by the BMCLA, the national competent authority, the approved label shall be traceable to the medicinal product.

4.10 If a medicinal cannabinoid concentrate or extract contains any added substances, the product shall be considered a medicinal cannabis product and labelled in accordance with this specification.

4.11 **IMPORTANT!** The container holding the medicinal cannabis product shall be properly labelled no matter how small. Additionally, any outer carton shall also be properly labelled. The label information required on each label shall be dependent upon the type of product and the point at which the medicinal product is being distributed.

4.12 Medicinal cannabis product shall display a barcode only once on the container. The barcode shall be rectangular in shape and not contain any image or design and shall be printed in black and white.

4.13 Where more than one label is placed on a medicinal cannabis product it should not affect the integrity of the "Track and Trace" system.

5 Labelling requirements

5.1 General

5.1.1 The following information shall appear on the front label/principal display panel of the package and carton of medicinal cannabis products as applicable.

5.1.2 A label shall not:

a) contain any untruthful or misleading statements including, but not limited to, health claims that are not supported by publicly available scientific evidence, or generally recognized scientific procedures and principles and for which there is significant scientific agreement among qualified scientific experts;

b) be attractive to minors, as stated in sub clause 6.5.

5.2 Product identity

5.2.1 The brand name and the medicinal cannabis product name shall be in **LARGE LETTERS**, in a size reasonably related to the most prominent printed matter on the front/principal display panel, and shall be parallel to the base on which the package is intended to stand or be displayed.

5.2.2 The scientific name and common name of the cannabis being packaged shall be indicated.

5.2.3 Where a name or names have been established for a medicinal cannabis product at least the international non-proprietary name (INN) shall be used at the point of sale or retail.

5.2.4 A "brand name" or "trade mark" may be used, provided it accompanies one of the names allowed by the national competent authority.

5.2.5 The product identity shall clearly identify whether the item is derived from cannabis.

5.2.6 The product identity for medicinal cannabinoid isolates, extracts and concentrates shall correctly identify whether the product is an isolate, extract or a concentrate.

5.2.7 The label shall state, additional words or phrases as necessary to avoid misleading or confusing the consumer, patient, or caregiver in regard to the true nature and physical condition of the medicinal cannabis product. This shall be done either in conjunction with, or in close proximity to the name of the medicinal cannabis product.

5.3 Net content declaration

5.3.1 The net contents of the medicinal product shall be declared in the metric system.

5.3.2 The net contents shall be provided on the front label/principal display panel and shall be declared in the following manner:

a) for liquid products, by volume;

b) for solid products, by weight;

c) for semi-solid or viscous products, either by weight or volume.

5.3.3 The net contents shall be accompanied by a correct statement of the net contents of the package, with respect to the number of discrete units, as applicable.

5.3.4 The net contents shall be the net quantity of the contents of all the packages in the Lot;

5.4 Potency labelling

5.4.1 The THC and CBD (and other cannabinoids) percentage composition values required to be declared on the medicinal cannabis product label shall be stated as per the certificate of analysis issued by a third party cannabis testing laboratory in accordance with the Regulations.

5.4.2 Potency values shall be expressed as per the analysis of the samples taken and tested by the designated analytical services laboratory in compliance with the national Regulations. A label shall not have a THC, CBD or other major active cannabinoid value which varies from the applicable concentration range by more than 10 percent as specified by the competent national authority.

5.4.3 For medicinal cannabis products with a limit less than the limit of quantification, the value on the label shall be declared as LOQ.

5.5 The Universal symbol

5.5.1 The Universal symbol, illustrated in Figure 1, shall be displayed on the principal display panel of the product label and used to inform and warn consumer, authorized patient or caregiver that the cannabis product contains THC. This symbol shall be located on the principal display panel and shall be at least 1.27 cm^2.

5.5.2 The Universal symbol shall be displayed on labels of all cannabis products containing THC in a concentration greater than 10 µg/g, taking into account potential to convert THCA into THC.

5.5.3 The Universal symbol shall be at least 12.0 mm in width by 9.0 mm in height. Alternatively, for small packages the symbol shall be scalable and meet the requirements of the Track and Trace system. The universal symbol shall be red, black, and white and cannot be changed from how it appears in the example provided. This symbol and authorization for its use shall be obtained from the BMCLA.

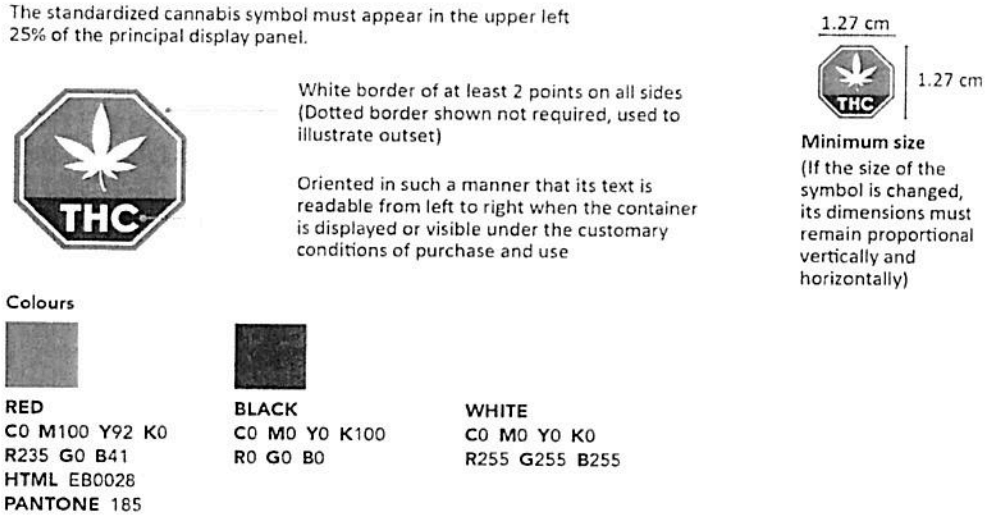

Figure 1 – Universal cannabis symbol

NOTE If the size of the symbol is changed, its dimensions shall remain proportional vertically and horizontally.

5.6 Medical grade symbol

5.6.1 If the product is a medical grade cannabinoid product, concentrate or extract processed by a licensee, or medical cannabis processing site, the medical grade symbol shall be displayed on the principal display panel.

5.6.2 The medical grade symbol shall be controlled by the Barbados Medicinal Cannabis Licensing Authority in conjunction with the Barbados Drug Service and made available to licensees. The medical grade symbol is a symbol that is **used only by licensees** that produce cannabinoid products, concentrates, or extracts that possesses a THC concentration that is above the recreational concentration limit.

5.6.3 The medical grade symbol, illustrated in Figure 2, shall be displayed and shall be at least 9.0 mm in diameter and can be obtained from the BMCLA.

Figure 2 – Medical grade symbol

5.6.4 **IMPORTANT!** The Medical grade symbol is used in addition to the Universal symbol – both symbols are required. The medical grade symbol shall appear on the principal display panel and be at least 9.0 mm in diameter. Any medical grade product should contain the warning "For use by Medicinal Cannabis Program patients only" rather than the recreational warning, "For use only by adults 21 years and older."

5.7 Required health warnings

5.7.1 Retail medicinal cannabis products shall declare the following warning on the label "For Use by adults 18 years and older. Keep out of the reach of children."

5.7.2 For medicinal cannabis, the following is required on the label: "For use by Authorized Medical Cannabis patients only. KEEP OUT OF THE REACH OF CHILDREN.

5.7.3 Additional medicinal cannabis health warning messages as set out in Annex 1 shall be used as applicable.

5.7.4 All point of sale materials and displays may carry the required health warning in the proportions required by this standard as set out in sub clause 6.7.3.

5.8 Additional labelling requirements (information panel)

On the label of each retail package and carton of medicinal cannabis products, the following additional information shall be declared:

5.8.1 Declaration of medical cannabis product active ingredients content and/or any other ingredients (as applicable)

5.8.1.1 A list of product contents shall be declared on the manufacturer's label of the processed medicinal cannabis product, except for single strain raw cannabis products;

NOTE Active ingredients shall be declared as required by this standard.

5.8.1.2 The list of ingredients shall be headed or preceded by the title "Ingredients" or "Contents" as appropriate.

5.8.1.3 The list of ingredients shall:

a) list all ingredients in descending order of percentage and volume or mass (if applicable) at the time of the production of the medicinal cannabis product;

b) Include any substance and processing aid used in the processing, preparing, manufacturing, packaging or holding of the medicinal cannabinoid product that is present in the final product, inclusive of any tinctures or release sprays;

c) Correctly identify the active ingredient in the medicinal cannabis product;

Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared as such in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of percentage and volume or mass (as applicable).

d) Ingredients known to cause hypersensitivity shall always be declared;

e) Where a product is produced in a facility where ingredients known to cause hypersensitivity are processed, it shall be stated on the label.

5.8.2 Name and identification details

5.8.2.1 The name, unique licensee identification number and complete address of the licensed cultivator, manufacturer and or retail distributor as applicable.

5.8.3 Date marking

5.8.3.1 The date of harvest, packaging or manufacturing as applicable.

5.8.3.2 The expiration date or a statement that no expiry date has been determined for non-retail raw cannabis products as applicable.

5.8.3.3 The date shall be printed on each package as follows: "mm (or mmm) yyyy", where "mmm" denotes the month expressed as the first three letters of the month and "yyyy" the year expressed in Arabic numerals.

5.8.3.4 The date specified in 5.8.3.1 and 5.8.3.2 shall appear in an area of the side panel of rectangular packages opposite the declaration area. Packages of other shapes shall declare the above information adjacent to the health warning. The information should ideally be printed in black on a white background or by means of contrasting colours and shall be clearly visible.

5.8.4 Lot Identification

A lot Identification number assigned by the licensee in conformance with requirements specified by the BMCLA preceded by one of the following designations:

a) "Lot number",

b) "Lot no",

c) "Lot" or

d) "L"

5.8.5 The unique identification number (UID)

The unique identification number (UID) from the competent authority for the purposes of the track and trace system.

5.8.6 Country of origin

5.8.6.1 The country of origin of the cannabis product shall be declared.

5.8.6.2 The country of origin of the product shall be declared as "Manufactured in.... (name of country)" or "Product of .. (name of country)" or "Produced in ... (name of country)".

5.8.7 Instructions for the appropriate storage of the product

Any special conditions for the storage of the product shall be declared on the label where such information is required to support the integrity of the product, and the validity of the date(s) thereon.

5.8.8 Instructions for use/application

Instruction for the appropriate use of the product, as it relates to mechanism of use and dosage instructions shall be declared.

NOTE Final dosing regimen is as prescribed by physician.

6 Packaging requirements

6.1 Requirements for packaging material

Opaque, sanitary, vacuum sealable polystyrene bags shall be utilized for harvested cannabis. Live plants shall be transported in sanitary, secure, breathable containers. Harvested cannabis may also be transported in security shipping containers.

6.2 Packaging requirements for harvested cannabis and cannabis plant seeds

6.2.1 Harvested cannabis and cannabis plant seeds shall be packaged in a secure sealable envelope/package capable of maintaining the seeds in a dry state.

6.2.2 All harvested medicinal cannabis plant biomass for further processing shall be packaged in an immediate container.

6.3 Immediate container requirements for plant biomass for further processing

The immediate container in which a medicinal cannabis biomass for further processing is packaged shall:

a) be opaque or non-transparent;

b) prevent contamination of the cannabis;

c) keep the cannabis dry, in the case of dried cannabis;

d) have a feature to provide the user with an assurance that package was not tampered with prior to receipt.

6.4 Requirements for packaging by cannabis product type

6.4.1 Cannabis extract – maximum quantity

The immediate container of a cannabis extract that is a medicinal cannabis product and that is not in discrete units shall:

a) not permit the extract to be easily poured or drunk directly from the container; and

b) dispenses no more than 10 mg of THC per activation, if the cannabis extract

   1) is in liquid form at a temperature of 22 ± 2 °C;

   2) is not intended to be consumed only by means of inhalation; and

   3) contains at least 10 mg of THC, taking into account the potential to convert THCA into THC.

6.4.2 Cannabis product container requirements

The interior and exterior surfaces and the panels of any container in which a medicinal cannabis product is packaged shall:

a) not display any advertising elements or images;

b) be one uniform colour. However, the colour of each surface and the panel may be different;

c) meet the following requirements for colour:

   1) it shall not have the lustre of metal or have metallic properties in the ink, such as Pantone Metallics or Pantone Premium Metallics;

   2) it shall not be fluorescent, have fluorescent properties in the ink or have pigments that absorb ultraviolet energy and transmit it as a longer wavelength;

   3) create a contrast with

      i. the yellow colour of the background of the health warning message; and

ii. the red colour of the standardized cannabis symbol;

d) be smooth in texture, without any raised features, embossing, decorative ridges, bulges or other irregularities;

e) not include any hidden features that are designed to change the appearance of the container, covering or panel, such as heat-activated ink or feature that is visible only through technological means except a feature intended to prevent counterfeiting;

f) not include any feature that is designed to change the surface area of the container or covering;

g) not be capable of emitting a scent or sound;

h) possess coverings that are transparent and colourless;

i) not include any cut-out windows.

6.4.3 Outermost container

6.4.3.1 The outermost container in which a medicinal cannabis product is packaged shall not contain:

a) food;

b) more than one strain of cannabis; or

c) more than one immediate container.

6.4.3.2 Packages shall protect the medicinal cannabis products they hold. Packages and containers that hold medicinal cannabis products shall protect those items from contamination and shall not expose the medicinal cannabis product to any toxic or harmful substance. Packages shall be child-resistant, air-tight and not permit premature deterioration due to exposure from humidity and air.

6.5 Child proof packaging

6.5.1 Medicinal cannabis products cannot be packaged in a manner that is attractive to children and young adults

The following items are considered "attractive to children" and are not permitted:

a) cartoons;

b) designs, brands, or names that resemble a non-cannabis product that is typically marketed to children;

c) symbols or celebrities that are commonly used to market products to children would be considered "attractive to children;"

d) images of children;

e) words that refer to products that are commonly associated with children or marketed by children and young adults.

6.5.2 Packages cannot appear similar to any consumer product typically marketed towards children or use the same types of symbols or designs that are used to market products to children.

6.5.3 All medicinal cannabis products, except live plants and seeds, shall leave the retail facility in a child-resistant package.

6.5.4 The medicinal cannabis product shall be packaged in a container that is child-resistant at the point of sale.

6.5.5 **IMPORTANT!** In order for a package to be considered child-resistant, the package shall be tested and certified as meeting the performance requirements and test method standards set out in ISO 8317: 2015 by a qualified, third-party testing firm.

NOTE 1 Child-resistant packages come in two forms: (1) single-use and (2) re-sealable or appropriately secured, continually child-resistant. A single-use, child-resistant package is one that meets the child-resistance standard for a single use and is child resistant until it is opened. A re-sealable, continually child-resistant package is one that is capable of being resealed or appropriately secured after being opened and maintains child-resistant properties throughout the life of the product.

NOTE 2 The type of child-resistant packaging required depends on the medicinal cannabis product being sold in the container. Live cannabis plants and seeds do not require the use of child-resistant packages.

6.5.6 Single dose medicinal cannabis products may be packaged in a single-use, child-resistant package. All other multi-dose medicinal cannabis products shall be packaged in a re-sealable, continually child-resistant package.

6.5.7 **IMPORTANT!** Products shall be package directly into containers that are Barbados Medicinal Cannabis Licensing Authority approved and certified child resistant.

6.6 Re-using packaging

Packaging can be re-used once they are able to be sanitized to meet Good Manufacturing Practices (GMPs) standards and other requirements for packaging of medicinal cannabis product.

NOTE Clause 6.6 relates to packaging for the transport of live plants and wholesale medicinal cannabis products.

6.7 Presentation of information

6.7.1 General

6.7.1.1 Labels on medicinal cannabis products shall be applied in such a manner that they shall not become separated from the container.

6.7.1.2 Statements required to appear on the label by virtue of this standard shall be clear, prominent, indelible and readily legible by the customer, authorized patient or caregiver under normal conditions of purchase and use.

6.7.1.3 The information appearing on the label shall be in any typed, legible font that is readily readable and contrast suitably with the background.

6.7.1.4 Where the container is covered by outer packaging, the outer package shall carry the necessary information.

6.7.1.5 The name and net content of the product including the applicable warning labelling in sub clause 5.7, shall appear on the front main panel of the label.

6.7.2 Small container label

6.7.2.1 Medicinal Cannabis products presented in containers whose size are void of sufficient space for a label that contains all the information required under this specification shall have a label printed on or affixed to the container that includes the following minimum declarations:

a) A principal display panel containing the net weight or volume, product identity and universal symbol;

b) Licensee business or trade name and license number or registrant business or trade name and registrant number;

c) Unique Identification (UID) number;

d) Concentration or amount of THC and/or CBD contained;

e) Required health warnings in the format outlined in sub clause 5.7.

6.7.2.2 A Medicinal Cannabis product that is intended for human and animal use and contained in a container with a complete available surface area of less than 51 mm^2 shall comply with the labelling requirements for medicinal cannabis products, with the exception of the "NOT FOR ORAL USE" warning if the product is not intended for oral administration, or the "USE PRODUCT AS PRESCRIBED BY PHYSICIAN".

6.7.2.3 Producers may use a peel-back or accordion label with the information required in subsection 5.8 provided that the patient, health care provider or care giver can easily identify that important information is declared therein.

6.7.2.4 Should the product be placed in a package or container that is being re-used it shall conform with sub clause 6.6 and the label shall always be replaced.

6.7.3 Health warning labels/messages

6.7.3.1 The cannabis health warning messages as outlined in Annex 2 shall be displayed on the principal display panel on each type of container of each type of medicinal cannabis product that is packaged as applicable.

6.7.3.2 Health Warnings shall comprise of a primary and secondary message in a yellow box to inform and warn consumers, authorized patient or caregiver of the potential health risks and effects of using cannabis.

6.7.3.3 The first sentence shall be in lower case letters and bold type preceded by the word 'WARNING' in upper case letters and bold type,

6.7.3.4 The health warning messages shall be displayed in rotation on each type of container of each brand name of the cannabis product that is packaged annually, to ensure that each message is displayed, to the extent possible, on an equal number of containers of that product.

NOTE Medicinal cannabis topical preparations are exempted from this requirement as they have a single health warning message.

6.7.4 Language

6.7.4.1 The labelling requirements specified in this standard shall be in the English Language or the official language(s) of the country in which the product is being sold.

6.7.4.2 Where the medicinal cannabis product is:

a) imported from a country or State whose native or primary language is not the English language; and

b) to be sold in the packaging which carries a label or labels which are not in the English language.

the licensee shall ensure that all declarations (requirements) as stipulated under the regulation are made in the English language.

6.7.4.3 All numbers relating to net content and weight stated on the label shall be given in Arabic numerals.

NOTE Arabic numerals are the ten digits 0, 1, 2, 3, 4, 5, 6, 7, 8 and 9.

6.7.4.4 Information shall be unobstructed and conspicuous.

6.7.5 Front/principal display panel

6.7.5.1 All containers that hold medicinal cannabis products for sale or transfer to a customer, authorized patient or designated caregiver shall have a front or principal display panel.

6.7.5.2 If a container holding medicinal cannabis products is placed within another container for retail sale or transfer to the customer, authorized patient or designated caregiver, both containers shall have a principal display panel in addition to the other labelling requirements in accordance with this specification.

6.7.5.3 The principal display panel shall contain the information outlined in sub clause 5.2 to 5.7 inclusive of the universal cannabis symbol and medicinal grade symbol (where applicable).

6.7.6 Registration of labels programme

Labels shall be registered with the national competent authority, as applicable.

Annex A
(informative)

Elements of the medicinal cannabis label

A package may have more than one principal display panel and, if so, all principal display panels shall be properly labelled.

The elements which shall appear on the principal display panel are:

a) the universal symbol;

b) the net weight or volume; and

c) the product identity.

All three elements shall be visible on the package in the same field of vision.

The product identity shall:

a) be in LARGE type,

b) be in a size reasonably related to the most prominent printed matter on the principal display panel,

c) be parallel to the base on which the package rests as it is designed and displayed;

d) clearly identify that the product is derived from cannabis

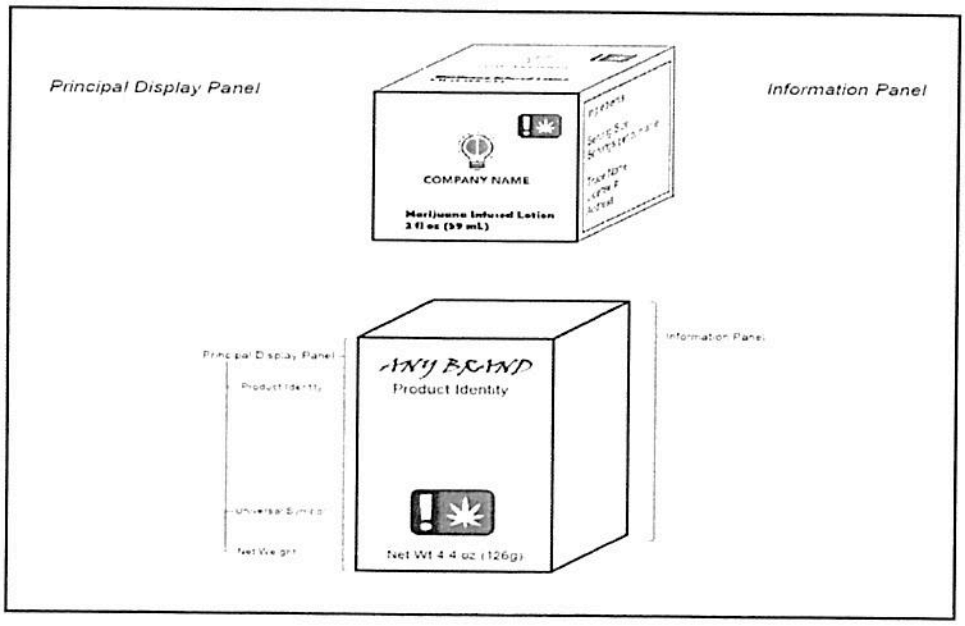

Figure 1 — Example of package with two principal display panels

Annex B
(informative)

Cannabis health warning messages

Part 1

All of the cannabis health warning messages in this Part apply to cannabis products of all classes of cannabis.

- WARNING: Do not use if pregnant or breastfeeding. Substances in cannabis are transferred from the mother to child and can harm your baby.
- WARNING: Do not drive or operate heavy equipment after using cannabis. Cannabis can cause drowsiness and impair your ability to concentrate and make quick decisions.
- WARNING: Frequent and prolonged use of cannabis containing THC can contribute to mental health problems over time. Daily or near-daily use increases the risk of dependence and may bring on or worsen disorders related to anxiety and depression.
- WARNING: Adolescents and young adults are at greater risk of harms from cannabis. Daily or near-daily use over a prolonged period of time can harm brain development and function.
- WARNING: The higher the THC content of a product, the more likely you are to experience adverse effects and greater levels of impairment. THC can cause anxiety and impair memory and concentration.
- WARNING: It can take up to 4 hours to feel the full effects from eating or drinking cannabis. Consuming more within this time period can result in adverse effects that may require medical attention.

Part 2

The cannabis health warning message in this Part applies only to cannabis products that are cannabis topicals.

- WARNING: Do not swallow or apply internally or to broken, irritated or itching skin. There may be health effects and risks associated with cannabis topicals that are not fully known or understood.

Part 3

Health warning messages for cannabis products that are dried cannabis or cannabis accessories that contain dried cannabis

- WARNING: Do not use if pregnant or breastfeeding. Using cannabis during pregnancy may harm your baby and result in low birth weight.
- WARNING: Do not use if pregnant or breastfeeding. Substances found in cannabis are also found in the breast milk of mothers who use cannabis.

- WARNING: Do not drive or operate machinery after using cannabis.
- WARNING: Do not drive or operate machinery after using cannabis. After cannabis use, coordination, reaction time and ability to judge distances are impaired.
- WARNING: Cannabis can be addictive. Up to half of people who use cannabis on a daily basis have work, social or health problems from using cannabis.
- WARNING: Cannabis can be addictive. 1 in 11 people who use cannabis will become addicted.
- WARNING: Cannabis can be addictive. Up to 1 in 2 people who use cannabis daily will become addicted.
- WARNING: Regular use of cannabis can increase the risk of psychosis and schizophrenia. Higher THC content can increase the risk of psychosis and schizophrenia.
- WARNING: Regular use of cannabis can increase the risk of psychosis and schizophrenia. Higher THC content can lower the age of onset of schizophrenia.
- WARNING: Regular use of cannabis can increase the risk of psychosis and schizophrenia. Young people are especially at risk.
- WARNING: Adolescents are at greater risk of harms from cannabis. Early and regular use increases the risk of psychosis and schizophrenia.
- WARNING: Adolescents are at greater risk of harms from cannabis. Using cannabis as a teenager can increase your risk of becoming addicted.
- WARNING: Adolescents are at greater risk of harms from cannabis. 1 in 6 people who start using cannabis in adolescence will become addicted.

Part 4

Health warning messages for all other cannabis products

- WARNING: Do not use if pregnant or breastfeeding. Using cannabis during pregnancy may harm your baby and result in low birth weight.
- WARNING: Do not use if pregnant or breastfeeding. Substances found in cannabis are also found in the breast milk of mothers who use cannabis.
- WARNING: Do not drive or operate machinery after using cannabis.
- WARNING: Do not drive or operate machinery after using cannabis. After cannabis use, coordination, reaction time and ability to judge distances are impaired.
- WARNING: Cannabis can be addictive. Up to half of people who use cannabis on a daily basis have work, social or health problems from using cannabis.
- WARNING: Cannabis can be addictive. 1 in 11 people who use cannabis will become addicted.
- WARNING: Cannabis can be addictive. Up to 1 in 2 people who use cannabis daily will become addicted.

- WARNING: Regular use of cannabis can increase the risk of psychosis and schizophrenia. Higher THC content can increase the risk of psychosis and schizophrenia.
- WARNING: Regular use of cannabis can increase the risk of psychosis and schizophrenia. Higher THC content can lower the age of onset of schizophrenia.
- WARNING: Regular use of cannabis can increase the risk of psychosis and schizophrenia. Young people are especially at risk.
- WARNING: Adolescents are at greater risk of harms from cannabis. Early and regular use increases the risk of psychosis and schizophrenia.
- WARNING: Adolescents are at greater risk of harms from cannabis. Using cannabis as a teenager can increase your risk of becoming addicted.
- WARNING: Adolescents are at greater risk of harms from cannabis. 1 in 6 people who start using cannabis in adolescence will become addicted.

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