Medicinal Cannabis Industry Australia

Code of Conduct

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Version 1.0 March 2020

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Contents

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1. About the Code

1.1 About MCIA

MCIA is the peak industry organisation for Australia's licensed medicinal cannabis industry. This encompasses all activities of cannabis licence holders across research, cultivation, production and manufacturing and interaction with the healthcare sector, medicinal cannabis supply chain and communities.

MCIA's focus is on building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients.

MCIA is providing stewardship for an economically sustainable and socially responsible industry that is trusted and valued by patients, the medical community and governments. The Australian industry and its products are built on sound science and underpinned by industry processes and standards that ensure patients, the medical community and governments have confidence in the sector and its products.

MCIA is the leading industry association promoting efficiency, integrity and professionalism in Australia's medicinal cannabis markets and provides leadership in advancing the interests and accountability of all licensed participants.

1.2 Introduction

- This Code has been developed by MCIA to assist the industry's growth and development through:
  - defining 'Australian quality'
  - MCIA members abiding by the Code
  - a commitment to transparency to provide regulators, the medical community, patients and other stakeholders with confidence in the medicinal cannabis industry and the products it produces
  - enabling patient access to 'Australian quality' products
- The Code is part of a wider regulatory framework for ensuring appropriate behaviour by Industry
- Federal and State Government regulations governing the medicinal cannabis industry, medicines and patient access, as well as external standards, shape the sector
- As such the Code refers to a range of existing regulations and standards in relation to specific elements of the Code outcomes
- The Code ensures that MCIA members are aware of, comply with and demonstrate compliance with relevant Federal and State regulations
- It is complemented and supplemented by a range of training and related programs to assist awareness of the ethical responsibilities of the Industry
- The Code is a minimum requirement and company practices may be to a higher standard than those identified in the Code

1.3 Preamble

- The Code contributes to a well-functioning medicinal cannabis industry and supports a commitment to increased transparency and accountability, improved quality and integrity of products, and enhanced regulatory and legislative compliance
- Stakeholders in the medicinal cannabis industry engaging with a MCIA member know that they abide by the Code and thus, are committed to best business practices and have a commitment to the integrity, reputation and growth of the medicinal cannabis industry in Australia
- MCIA members are recognised as complying with the Code and committed to developing and operating in an industry that is built on trust, accountability, and assurance that practices are in compliance with the law
- The Code aims to promote high standards of integrity across the medicinal cannabis Industry so that patients and healthcare professionals can have confidence in their dealings with the Industry, its members and their products
- The Code provides a set of minimum expectations. Individual companies may have a higher expectation and subscribe to a higher set of standards

1.4 Medicinal cannabis supply chain

The medicinal cannabis supply chain is developing, however, it can be generally represented as per Figure 1. MCIA members may be involved in part or all of the supply chain and, as such, the Code applies to them as appropriate to their activities in the sector.

The behaviour obligations apply to all MCIA members.

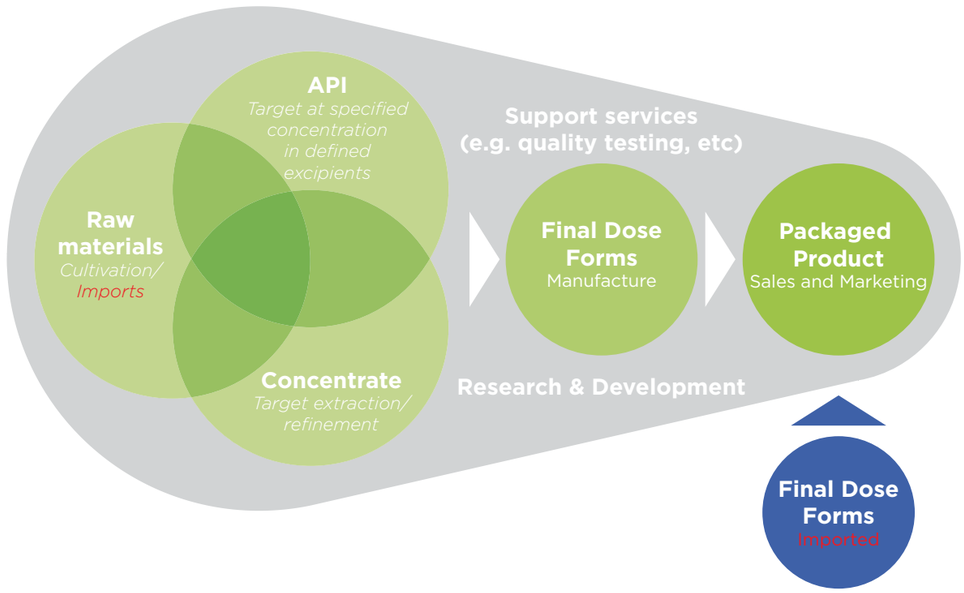

Figure 1: A generalised representation of the Medicinal Cannabis supply chain to represent the key areas in which the industry and its members operate

1.5 Code framework

A summary level representation of the Code and how it is influenced by the external regulatory framework is detailed in Figure 2.

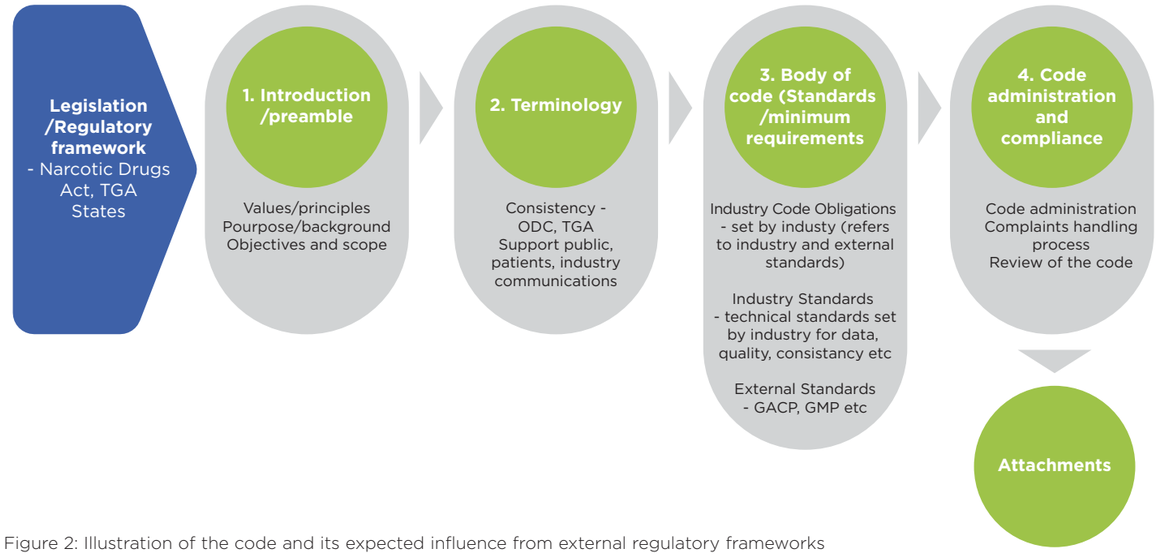

Figure 2: Illustration of the code and its expected influence from external regulatory frameworks

1.6 MCIA values - The MCIA promise

The Code has been developed on a foundation of key values and expected behaviours. The Code documents expectations around these values and behaviours with the objective being to underpin a promise that stakeholders, including patients, can trust MCIA members and their products. These key values and behaviours include:

- Authenticity
- Reliability
- Legal
- Ethically

MCIA members are held to strict regulatory requirements. Any medicine manufactured by an MCIA member has been derived from the cannabis plant and has been subject to stringent quality and safety standards, meaning patients will get what is promised.

1.7 Purpose and scope of the Code

- The Code is a voluntary, self-regulatory code applying to all MCIA members
- Members are required, as a condition of membership in MCIA, to observe all provisions of the Code
- The Code is not intended to provide, nor shall it be construed as, legal advice; or to take precedence over any relevant law or regulation. To the extent that any provision of the Code conflicts with a law or regulation, that law or regulation will prevail
- The Code is aimed at delivering confidence, increased transparency and accountability i.e. stakeholders engaging with a MCIA member know that the Member:
  - operates in in compliance with the law
  - are committed to best business practices
  - are committed to the integrity, reputation and growth of the medicinal cannabis industry in Australia
  - promotes a high standard of integrity so that patients and healthcare professionals can have confidence in the Industry and its products
- The Code provides the guidance for the medicinal cannabis supply chain and MCIA members to deliver on its value proposition for patients including in relation to:
  - Products which are
    - plant derived
    - of known quality
    - true to label
  - Business practices which are
    - compliant with all federal and state regulations
    - ethical
    - The Australian medicinal cannabis industry will deliver products that are:

Australian Quality

Plant Derived + Regulated + True to Label + Trusted

Innovative and developed & delivered with a sector that demonstrates ethical behaviour

2.0 Terminology

Cannabis drug means:
(a) cannabis; or
(b) cannabis resin; or
(c) extracts of cannabis; or
(d) tinctures of cannabis; or
(e) another drug that includes, or is from, any part of the cannabis plantz

Cannabis plant means the following:
(a) Any plant of the genus Cannabis
(b) Any part of a plant of the genus Cannabis including but not limited to, the seeds, stems or leaves of the plant

Cannabis resin means the separated resin, whether crude or purified, obtained from the cannabis plant

Code means The Medicinal Cannabis Industry Australia Code of Conduct

Convention means the Single Convention on Narcotic Drugs 1961, done at New York on 30 March 1961, as amended by the Protocol and as in force from time to time

Cultivate a cannabis plant includes the following:
(a) Sow a seed of a cannabis plant;
(b) Plant, grow, tend or nurture a cannabis plant;
(c) Graft, divide or transplant a cannabis plant;
but does not include the separation of cannabis or cannabis resin from a cannabis plant

Handling includes stacking, stowing, storing, transporting, loading, unloading and any operation incidental to, or arising out of, any of those operations

Licence means the following:
(a) A medicinal cannabis licence; and/or
(b) A cannabis research licence; and/or
(c) A manufacture licence
issued under the ND Act

Licensed premises means premises at which activities authorised under a Licence take place

Manufacture means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs

Medicinal Cannabis Product means a product, including but not limited to a substance, composition, preparation or mixture, that:
(a) Includes, or is from, any part of the cannabis plant; and
(b) Is for use for the purposes of curing, or alleviating the symptoms of, a disease, ailment or injury.

ND Act or **Act** means the Narcotic Drugs Act 1967 (Cth)

Permit means the following:
(a) A cannabis research permit; and/or
(b) A medicinal cannabis permit; and/or
(c) A manufacture permit; and/or
issued under the ND Act

Premises includes the following:
(a) A structure or building
(b) A vehicle, vessel or aircraft
(c) A place (whether or not enclosed or built on), including a place situated underground or under water
(d) A part of a thing referred to in paragraph (a), (b) or (c)

Preparation means a mixture, solid or liquid, containing a drug

Production consists of harvest and placing in a container for the purpose of manufacture or research

Supply includes the following, whether free or charge or otherwise:
(a) Supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase
(b) Supply by way of sample
(c) Supply in the course of testing safety or efficacy
(d) Supply by way of administration to, or application in the treatment of, a person

3.0 Code Requirements

The Code describes the practices and standards that underpin the delivery of Australian quality, plant derived medicinal cannabis products to patients. Activities and standards are described around the key elements identified in the preceding section.

There are a number of processes that occur in various parts of the supply chain and thus, apply at more than one point in the supply chain. This includes activities such as:

- compliance with applicable regulations
- training
- documentation of procedures
- collection of data
- maintenance of records
- adequate quality systems

The Code covers activities that an MCIA member undertakes that are subject to control via their medicinal cannabis license obligations.

3.1 Legislative and Regulatory Requirements

Medicinal cannabis products are regulated by the Federal Department of Health through:

- the Office of Drug Control (ODC), which administers the Narcotic Drugs Act 1967 Cth (ND Act) that regulates controlled substances to prevent diversion and illicit use

- the Therapeutic Goods Administration (TGA), which administers the Therapeutic Goods Act 1989 Cth that regulates, amongst other elements, the quality, safety and efficacy of medicines as well as access to medicines that have not been approved for general use

- relevant State and Territory legislation that applies to the medicinal cannabis industry, where the State and Territory governments have a role through medicine scheduling and particular requirements on how controlled drugs including medicinal cannabis may be authorised to be held, handled, supplied, destroyed or used in their jurisdiction including:
  - State and Territory Departments
  - Victoria: The Office of Medicinal Cannabis, Department of Health and Human Services
  - New South Wales: Ministry of Health
  - Western Australia: Department of Health
  - Queensland Health
  - South Australia: SA Health, Department for Health and Wellbeing
  - Tasmania: Department of Health and Human Services
  - Northern Territory: Department of Health
  - Australian Capital Territory: ACT Health
  - State and Territory legislation and regulations listed in Appendix 1

In addition, there are a range of other supporting legislative and regulatory requirements that medicinal cannabis companies should comply with. Adherence to the Code in no way reduces a company's responsibilities to comply with the Competition and Consumer Act, Privacy Act 1988 and other legal requirements. It is a company's responsibility to be aware of understand their legal obligations.

Generally, medicines supplied in Australia must be approved for general use through entry in the Australian Register of Therapeutic Goods (ARTG). However, the Therapeutic Goods Act provides several pathways for approved access to medicines that are not registered on the ARTG. These pathways include:

- Special Access Scheme (SAS)
- Authorised prescribers
- Clinical trials (CTN or CTX)

Medicinal cannabis products can come to market under any one of these pathways.

3.2 Plant derived

This element refers to those activities that relate to development of Australian quality, plant derived and legal products.

The Code requires that any cannabis derived medicine, or input to a medicine, cultivated or manufactured by an MCIA member has been derived from the cannabis plant and has been subject to stringent quality and safety testing.

The Code promotes that practices relating to raw cannabis materials and products that:

i. Reflect best management practices in particular in relation to hygiene/cleanliness, prevention of contamination, identification, cultivation, documentation, quality and legal obligations e.g. good agricultural practice (GAP) or good agriculture and collection practices (GACP) or implement their own processes that are equivalent. This includes an inherent expectation that where there is deviation from a standard and defined practice that this information is passed along to any stakeholders to which this is relevant.

   GAP or GACP are a set of practices/guidelines that help ensure/improve the safety and quality standards of raw materials used in the preparation of medicinal cannabis products.
   Reflecting the early stage development of the industry, MCIA members will have a period of time to demonstrate compliance. This minimum requirement and subsequent sections of the Code will deliver full supply chain GMP.

ii. Comply with TGO 93

   Unapproved medicinal cannabis products imported into and supplied/manufactured in Australia must conform with Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 (TGO 93). TGO 93 is a standard that specifies minimum quality requirements for medicinal cannabis products.

iii. Where required, comply with good manufacturing practice (GMP) as related to the jurisdiction of interest e.g. Australia, EU

iv. Are supported by data to meet requirements of GMP

3.3 Australian quality / regulated / true to label

This element refers to those activities that relate to providing assurance and/or confidence in relation to medicinal cannabis products.

The Code ensures that practices relating to medicinal cannabis products/product variations are produced in a manner that provides assurance to healthcare professionals, patients, regulators and the community. The Code requirements are in the table below.

It should be noted that MCIA members operate at different parts of the supply chain and thus, not all the elements below will necessarily apply to all members. It is a member's responsibility to identify which elements they should be compliant with.

Assurance/outcome	Code Practice/Requirement	Standard/ Ref document[1]
Clean/safe/ stability	Raw materials production aligned with good agricultural practices (refer 3.2) Produced in compliance with good manufacturing practice as related to the jurisdiction of interest and compliant with pharmacovigilance obligations as part of ongoing safety surveillance.	TGO93[2] GMP EU GMP
Truth in label i.e. product is what is claimed	Accurately labelled as required by the relevant standard, and to most accurately reflect the product. Listed in accordance with ARTG or other standard requirements as appropriate and to provide appropriate communication to the patient and doctor in relation to its use as a medicine.	TGO91 TGO92 TGO93 GMP
Data to support labels and available for verification	Data to back up labels and substantiate the products safety, stability and origin should be easily retrievable so that it can supplied on request within a reasonable timeframe e.g. stability, pesticides, contaminants, composition, expiry, etc as required by relevant standard. Further to the information supplied or generally available, a company should, upon reasonable request and within reasonable scope, provide doctors/ healthcare professionals with additional accurate and relevant information about products, including company information.	Certificate of analysis Stability data TG093 ICH Q1A, Q1B, Q3A, Q6A
Supplied in a secure manner	Supplied through secured supply chains that are in accordance with medicines/poisons requirements. Supplied in accordance with Quality Risk Management and Pharmaceutical Quality System requirements and guidelines.	TG093 EU GMP ICH Q9. Q10
Verifiable - Australian quality, diversion,	Supported by quality systems to verify: - Australian quality - product compliance with medicines/poisons requirements - compliance with diversion requirements under licence/ permit	ODC TG093 GMP ICH Q7
Ethical and appropriate advertising	Marketed in accordance with TGA advertising guidelines and in a responsible and appropriate manner and in accordance with Section 3.4 of this Code.	

[1] Links to relevant documents and websites are provided in Attachment 1.

[2] Unapproved medicinal cannabis products imported into and supplied/manufactured in Australia must conform with Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 (TGO 93). TGO 93 is a standard that specifies minimum quality requirements for medicinal cannabis products.

3.4 Behaviour

MCIA members commit to interacting with our stakeholders and communities consistent with the following principles:

- The well-being of patients is the first priority for MCIA members
- MCIA members' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner that would have an inappropriate influence
- MCIA members are responsible for providing accurate, balanced, and scientifically valid data on products as appropriate e.g. -to doctors, etc
- Information and education must be ethical, accurate, balanced and not be misleading. Information in materials must support assessment of the risks and benefits of the product
- MCIA members will respect the privacy and personal information of patients and healthcare professionals

The objective of this Code and the sections referenced below are to build and retain trust and confidence by patients, health care professionals and other stakeholders in the medicinal cannabis industry.

MCIA members should adhere and behave consistent with the spirit[3] of the Medicines Australia Code of Conduct, and in particular the following sections:

PART B – Ethical interactions with Healthcare Professionals
1. Requirements for promotional claims directed at healthcare professionals
   1.1 Substantiating Data
2. Requirements for material directed to healthcare professionals
   2.1 Required inclusions for materials including promotional claims
   2.2 Minimum Product Information (MPI)
   2.3 Required inclusions for product-related materials that do not include promotional claims
   2.4 Content hosted online
   2.5 Social Media
   2.6 Prescribing Software
3. Educational Material for Healthcare Professionals
4. Events
   4.1 Company Educational Events Held in Australia
   4.2 Third Party Educational Events Held in Australia
   4.3 Trade Displays
   4.4 Sponsorship of Healthcare Professionals to Attend Educational Events
   4.5 Hospitality, Travel and Accommodation

PART C – Ethical Interactions with relevant stakeholders
11. Appropriate Communications with Relevant Stakeholders
12. Support for Health Consumer Organisations

PART D – Ethical Interactions with Patients and the General Public
13. Interactions with the General Public
    13.1 Promotion of Medicine Delivery Devices to the General Public
    13.2 Educational Information and Disease Awareness
14. Patient Support Programs (PSPs)

PART E – Transparency of interactions with Healthcare Professionals and with Consumers
15. Transparency Reporting
    15.1 Transfers of Value to Healthcare Professionals
    15.2 Reporting of Sponsorship of Third Party Educational Meetings and Symposia
    15.3 Reporting of Health Consumer Organisation Support
    15.4 Reporting Schedule

The behaviour of MCIA members must never be such as to bring discredit upon, cause reputational damage to, or reduce confidence in the medicinal cannabis industry.

[3] This recognises that the Medicines Australia Code language, expectations and specifics are geared towards registered medicines and that products released under special access schemes, by definition, do not have the full breadth of supporting material, data behind them, and other aspects (such as Section 2) are largely unavailable to a company with an unregistered medicine.

3.5 Training

The Code encourages professional development through the continual development of training for staff to maintain high professional standards.

All staff are to be adequately trained in the requirements of this Code.

While specific training required will differ across the supply chain and depend on tasks undertaken, companies have a responsibility to maintain high standards of ongoing training to ensure that all principals and staff:

- are trained and given clear guidance so they can competently and efficiently discharge their functions and provide the services they are authorised to provide
- have adequate knowledge of the provisions of this Code
- have completed and keep up to date training relevant to their roles - either formal or informal on the job training
- comply with all relevant industry regulations and/or standards
- maintain documented evidence of training completed

3.6 Complaints

- Customer/patient complaint[4]

  MCIA members will have in place a procedure for dealing with any patient/customer complaint which may include reference to Australian Standard "Customer Satisfaction - Guidelines for complaints handling in organisations" (GMP, ISO 10002:2004, MOD).

- Complaints against a Code signatory

  In the first instance any complaint about the conduct of a Code signatory should be referred to that Code signatory who should be allowed a reasonable time to address or resolve the complaint.

  If the complaint is not resolved to the complainant's satisfaction the complainant should contact the Code Compliance Officer who can advise whether the complaint falls under the jurisdiction of this Code and the MCIA Board of Directors.

  Any complaint will be dealt with in accordance with the Complaint Handling Guidelines.

[4] Any person (MCIA member, non member or other stakeholder) may raise a complaint if believe that a MCIA member is not abiding by the Code. All complaints will be directed to the member to whom the complaint is directed to resolve in the first instance

4.0 Code administration

The Code will be administered by MCIA who will provide guidance to all members about the operation and requirements of the Code. MCIA will also be responsible for:

- managing the administration process
- reviewing compliance against the Code
- overseeing promotion of the Code
- developing guidance and support material on the Code to assist members to comply with the Code
- handling complaints in accordance with the process for handling complaints
- preparing an annual report on the Code's operations

The Code will be regularly reviewed and updated to keep pace with changes in technology, business practice and community expectations.

References/Links

Agencies

Australian Government, Department of Health, Office of Drug Control (ODC)
https://www.odc.gov.au/medicinal-cannabis

Australian Government, Department of Health, Therapeutic Goods Administration (TGA)
https://www.tga.gov.au/

United Nations Office on Drugs and Crime (UNODC)
https://www.unodc.org/

Legislation, Regulations & Standards

Narcotic Drugs Act 1967
https://www.legislation.gov.au/Series/C1967A00053

Narcotic Drugs Amendment Act 2016
https://www.legislation.gov.au/Series/C2016A00012

Narcotic Drugs Regulation 2016
https://www.legislation.gov.au/Series/F2016L01613

Customs (Prohibited Exports) Regulations 1958
https://www.legislation.gov.au/Series/F1996B03403

Customs (Prohibited Imports) Regulations 1956
https://www.legislation.gov.au/Series/F1996B03651

Narcotic Drugs (Licence Charges) Act 2016
https://www.legislation.gov.au/Series/C2016A00075

Narcotic Drugs (Licence Charges) Regulation 2016
https://www.legislation.gov.au/Series/F2016L01893

Therapeutic Goods Act 1989
https://www.legislation.gov.au/Series/C2004A03952

Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) (TGO93)
https://www.tga.gov.au/publication/poisons-standard-susmp

Standard for the Uniform Scheduling of Medicines and Poisons No. 24 June 2019 (Poisons Standard)
https://www.legislation.gov.au/Series/F2019L00685

Therapeutic Goods (Microbiological Standards for Medicines) Order No. 100 2018 (TGO100)
https://www.legislation.gov.au/Series/F2018L01685

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
https://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

European Pharmacopoeia
https://www.edqm.eu/en/european-pharmacopoeia-ph-eur-9th-edition

British Pharmacopoeia
https://www.pharmacopoeia.com/

UNODC Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products (ST/NAR/40)
https://www.unodc.org/unodc/en/scientists/recommended-methods-for-the-identification-and-analysis-of-cannabis-and-cannabis-products.html

Single Convention on Narcotic Drugs 1961
https://www.unodc.org/unodc/en/commissions/CND/conventions.html

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products (GMP)
https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products

European Union Good Manufacturing Practices (EU GMP)
https://ec.europa.eu/health/documents/eudralex/vol-4_en

Drugs, Poisons and Controlled Substances Act 1981 (Vic)
https://www.legislation.vic.gov.au/in-force/acts/drugs-poisons-and-controlled-substances-act-1981/130

Drugs, Poisons and Controlled Substances Regulations 2017 (Vic)
https://www.legislation.vic.gov.au/in-force/statutory-rules/drugs-poisons-and-controlled-substances-regulations-2017/011

Access to Medicinal Cannabis Act 2016 (Vic)
https://www.legislation.vic.gov.au/as-made/acts/access-medicinal-cannabis-act-2016

Poisons and Therapeutic Goods Act 1966 (NSW)
https://www.legislation.nsw.gov.au/#/view/act/1966/31/full

Poisons and Therapeutic Goods Regulations 2008 (NSW)
https://www.legislation.nsw.gov.au/#/view/regulation/2008/392/full

Misuse of Drugs Act 1981 (WA)
https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_609_homepage.html

Misuse of Drugs Regulations 1982 (WA)
https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_1823_homepage.html

Drugs Misuse Act 1986 (QLD)
https://www.legislation.qld.gov.au/view/html/inforce/2018-03-29/act-1986-036

Health (Drugs and Poisons) Regulation 1986 (QLD)
https://www.legislation.qld.gov.au/view/html/inforce/2018-03-09/sl-1996-0414

Controlled Substances Act 1984 (SA)
https://www.legislation.sa.gov.au/LZ/C/A/CONTROLLED%20SUBSTANCES%20ACT%201984.aspx

Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2014 (SA)
https://www.legislation.sa.gov.au/LZ/C/R/Controlled%20Substances%20(Controlled%20Drugs%20Precursors%20and%20Plants)%20Regulations%202014.aspx

Misuse of Drugs Act 2001 (Tas)
https://www.legislation.tas.gov.au/view/whole/html/inforce/2015-04-22/act-2001-094

Poisons Act 1971 (Tas)
https://www.legislation.tas.gov.au/view/html/inforce/current/act-1971-081

Poisons Regulations 2018 (Tas)
https://www.legislation.tas.gov.au/view/html/inforce/2019-04-17/sr-2018-079

Misuse of Drugs Act 1990 (NT)
https://legislation.nt.gov.au/en/Legislation/MISUSE-OF-DRUGS-ACT-1990

Misuse of Drugs Regulations 1990 (NT)
https://legislation.nt.gov.au/Legislation/MISUSE-OF-DRUGS-REGULATIONS-1990

Medicines, Poisons and Therapeutic Goods Act 2008 (ACT)
https://www.legislation.act.gov.au/a/2008-26/

Medicines, Poisons and Therapeutic Goods Regulation 2008 (ACT)
https://www.legislation.act.gov.au/sl/2008-42