Queensland

MDMA-Assisted Psychoactive Therapy for PTSD Victims Youth Act 2021

Youth Act No. 4 of 2021

Legalisation of MDMA for use in medical research and regulation for use in medical therapies to treat PTSD

[Assented to 13 October 2021]

Queensland

MDMA-Assisted Psychoactive Therapy for PTSD Victims Youth Act 2021

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The Youth Parliament of Queensland enacts—

Part 1 Preliminary

1 Short title

This Youth Act may be cited as the *MDMA-Assisted Psychoactive Therapy for PTSD Victims Youth Act 2021*.

2 Commencement

This Youth Act commences on a day to be fixed by proclamation.

3 Main purpose of Youth Act

The main purpose of this Youth Act is to legalise and regulate the use of medicinal MDMA for the treatment of PTSD in conjunction with psychotherapy.

4 Definitions

In this Youth Act—

Authorised person

(a) A health professional;

(b) An officer of the Queensland police; or

(c) In the context of a patient undergoing a treatment process at a facility under Part 6 of this Youth Act, a member of the facility staff who has been authorised by a health professional to supervise the patient.

Culpable non-compliance non-compliance that is intentional or non-compliance to which section 328 of the *Criminal Code Act 1899* (Qld) applies.

Drugs an ingestible substance that alters a person's mental state

Eligible patient a person who has been deemed eligible under s 18 of this Youth Act, and to whom section 18A of this Youth Act does not apply, and who is a patient.

Innocent non-compliance non-compliance that is not intentionally non-compliant or culpably non-compliant.

Licenced prescriber A person who holds a valid QMP licence

MDMA 3 ,4-Methylenedioxymethamphetamine manufactured with the intent for PTSD treatment

Patient, a person intending to, who has undertaken, is undertaking or has been selected to undertake treatment under this Youth Act whether for research or clinical use.

Prescriber means the person responsible at any particular time for prescribing MDMA to a particular patient.

Psychotherapy therapy consisting of part medicated treatment and part psychological treatment

Treatment MDMA-assisted psychotherapy as outlined in Part 6

Part 2 Establishment of Regulatory Body

5 Objective

This part is intended to safeguard the future production of MDMA and regulate its clinical use and research within Queensland.

6 Establishment of the Regulatory Body

(1) The Queensland Psychoactive Drug Division (QPDD) will be established as a subsidiary of Queensland Department of Health

(2) The Queensland Department of Health, in conjunction with existing board members will appoint a regulatory board of minimum 4 and maximum 10 persons to sit as members of the Queensland Psychoactive Drug Division (QPDD) board -

(a) The board will include industry professionals with a minimum 5 years industry experience inclusive of -

(i) Pharmaceutical/pharmacological manufacturers;

(ii) Medical doctors with experience in pharmacology, psychiatry, psychology, neurology, trauma therapy and/or any relevant medicinal fields; and

(iii) Psychologists (with and without clinical experience).

(3) The QPDD are responsible for -

(a) The management of MDMA manufacturing and distribution;

(b) Ensuring MDMA manufacturers adhere to industry and legislative standards;

(c) The facilitation of MDMA research;

(d) The regulation of MDMA prescription and usage; and

(e) Managing the implementation of any future psychoactive drugs.

(4) The QPDD hold the following powers -

(a) Issue Queensland MDMA manufacturers (QMM) licences;

(b) Issue Queensland MDMA prescriber (QMP) licences;

(c) Revoke QMM/QMP licences;

(d) Conduct unannounced and scheduled audits; and

(e) Issue suspensions of licences issued by the QPDD

(5) The Queensland Department of Health has the power to amend the powers of the QPDD at any time.

Part 3 MDMA Manufacturing

7 Licence to Manufacture MDMA

(1) A valid Queensland MDMA manufacturers (QMM) licence must be carried to manufacture MDMA in Queensland.

(2) To obtain a QMM licence, applicants must -

(a) Comply with the Good Manufacturing Principles (GMP) outlined by the Commonwealth Therapeutic Goods Administration (TGA);

(b) Be granted a permit to manufacture MDMA by the Commonwealth Office of Drug Control; and

(c) Follow the application process as outlined by the QPDD.

(3) QMM licences are valid for two years.

8 QMM Licence Regulations

(1) The purpose of stringent QMM licence regulations is to ensure-

(a) The MDMA produced is of high quality and safe for clinical use;

(b) Appropriate manufacturing processes; and

(c) The continued development of MDMA manufacturing to increase efficiency.

(2) QMM licence regulations are to be legislated by the Queensland Health Minister in consultation with -

(a) Chief of Queensland Health;

(b) QPDD; and

(c) Queensland Mental Health Commission

(3) QMM licence regulations will amend the -

(a) *Health Act 1937*; and

(b) *Health (Drugs and Poisons) 1996 Regulation*.

(4) The Queensland Health Minister must introduce the amendments to Parliament within 180 days of assent of this Youth Act.

(5) Until the QMM licence regulations have been implemented, no QMM licences are to be granted.

(6) QMM licence holders will be required to follow regulations outlined in -

(a) *Health Act 1937*; and

(b) *Health (Drugs and Poisons) 1996 Regulation*.

9 Audit Process of QMM Licence Holders

(1) Manufacturers will undergo compulsory bi-annual audits without prior notice to -

(a) Ensure QMM licence regulations are being adhered to;

(b) Inspect the manufacturing conditions;

(c) Assess the quality of the drug; and

(d) Assess the safety of the drug.

(2) Audits will be undertaken by -

(a) QPDD; or

(b) An independent body nominated by QPDD

(3) Representatives of the body undertaking the audit will randomly select five 20g samples of completed MDMA product to be tested off-site.

(4) Audit standards will be determined by the QPDD and graded as;

(a) Pass; or

(b) Fail

10 Non-Compliance with QMM licence regulations

(1) A manufacturer will be deemed non-compliant by the QPDD if -

(a) The manufacturer fails two consecutive audits; or

(b) A patient using the manufacturer's product suffers severe health consequences including -

(i) Death ;

(ii) Permanent disablement; and/or

(iii) Severe medical emergencies;

as a result of using the manufacturer's product during treatment regulated by this Youth Act.

(2) If a manufacturer is deemed non-compliant they will -

(a) Be subject to a QPDD investigation;

(b) Be required to immediately cease production; and

(c) Have their QMM licence suspended.

(3) The QPDD investigation will classify manufacturers as -

(a) Compliant;

(b) Innocently non-compliant;

(c) Culpably non-compliant.

(4) Compliant manufacturers will have their QMM licence reinstated.

(5) Innocently non-compliant manufacturers will -

(a) Have their QMM licence suspended for a period of four to twelve months;

(b) Be subject to monthly audits for a period of two years from the date of the suspension of their licence.

(6) Culpably non-compliant manufacturers will -

(a) Have their QMM licence revoked;

(b) Permanently ineligible to reapply for a QMM licence;

(c) Be required to surrender all -

(i) Manufacturing equipment/supplies;

(ii) MDMA; and

(iii) Any other goods associated with the production of MDMA.

(d) Surrendered goods will remain in the care of the QPDD and be-

(i) Destroyed; or

(ii) Handled at the discretion of the QPDD.

(7) The QPDD will assess any compensation for surrendered property at their discretion, but may take into consideration the manufacturer's culpability, how closely the surrendered items are linked with the manufacture of MDMA, and whether the items surrendered were used for illicit purposes associated with the manufacture of MDMA.

(8) In an assessment of compensation under section 10 (7) of this Youth Act, the default value of compensation will be the full market value of the surrendered items, and the QPDD deems that compensation should be less that that amount and assesses compensation accordingly, then the QPDD must provide written reasons for this decision to the manufacturer.

11 Appeals Process

(1) Only the following QPDD decisions may be appealed -

(a) Audit grade; and

(b) Non-compliant decision.

(2) Appeals must be made in writing to the QPDD within 10 working days of the original decision.

(3) Appeals made by manufacturer must be accompanied by -

(a) A statement outlining the error the manufacturer believes was made by the QPDD; and

(b) Supporting documentation.

(4) Appeals will be forwarded to the Queensland Health Internal Audit Division.

(5) Until the appeal is resolved the manufacturer must abide by the original decision made by the QPDD -

(a) This includes if a licence has been suspended.

(6) An exception to section 10(2) of this Youth Act is if a manufacturer has been deemed innocent non-compliant:

(a) The manufacturer is not required to surrender all manufacturing goods;

(b) The manufacturer will not have their QMM licence revoked; and

(c) The manufacturer will have their QMM licence suspended.

Part 4 Prescription of MDMA

12 Licence to Prescribe MDMA

(1) A valid Queensland MDMA prescribers (QMP) licence must be obtained to prescribe MDMA in Queensland and become a licenced prescriber.

(2) To obtain a QMP licence, applicants must -

(a) Be a licenced psychiatrist with -

(i) A minimum of 4 years clinical experience; and

(ii) A background in psychological trauma treatment.

(b) Be a State and/or private mental health facility with the ability to -

(i) House patients for a minimum of 14 days

(ii) Have access to psychiatric and neurological assistance

(iii) Comply with any delegated legislative decisions made by the QPDD

(c) Follow the application process as outlined by the QPDD.

(d) Complete a specialised training program (to be created by QPDD); which will include assessment and examination procedures.

(3) QMP licences are valid for five years.

13 QMP Licence Regulations

(1) The purpose of stringent QMP licence regulations is to ensure-

(a) High quality treatment; and

(b) The responsible prescription of MDMA.

(2) QMP licence regulations are to be legislated by the Queensland Health Minister in consultation with -

(a) Chief of Queensland Health;

(b) QPDD; and

(c) Queensland Mental Health Commission

(3) QMP licence regulations will amend the -

(a) *Health Act 1937*; and

(b) *Health (Drugs and Poisons) 1996 Regulation*.

(4) The Queensland Health Minister must introduce the amendments to Parliament within 180 days of assent of this Youth Act.

(5) Until the QMP licence regulations have been implemented, no QMP licences are to be granted.

(6) QMP licence holders will be required to follow regulations outlined in -

(a) *Health Act 1937*; and

(b) *Health (Drugs and Poisons) 1996 Regulation*.

14 Responsibility of QMP Licence Holders

(1) QMP licence holders will be responsible for -

(a) Providing treatment to patients prior to prescribing MDMA;

(b) Responsibly prescribing MDMA following the regulations outlined in this Youth Act;

(c) Creating and managing the treatment plan of patients;

(d) Ensuring MDMA is administered in accordance with the regulations outlined in this Youth Act;

(e) Collecting and managing patient results; and

(f) Ensuring the patient receives appropriate aftercare.

(2) To ensure appropriate care throughout all stages of treatment the licenced prescriber must -

(a) Provide services to the patient over three continuous phases for a minimum of 12 months -

(i) Pre-treatment phase minimum six months;

(ii) Treatment phase minimum three months; and

(iii) Post-treatment phase minimum five months.

(b) Maintain regular contact with patients to ensure progress -

(i) At least once a week via phone or email; and/or

(ii) At least once a month in person.

(c) After discharge from the facility post treatment, the licenced prescriber must make phone contact daily for a period of one week.

15 Assessment of QMP Licence Holders

(1) To ensure the licensed prescriber is providing high quality care to patients, patients will be required to complete an anonymous survey at the completion of their treatment -

(a) This survey will be created by the QPDD;

(b) The results will be collected by the QPDD; and

(c) Anyone outside the QPDD, including licenced prescribers, will have no access to patient responses.

(2) If a licenced prescriber receives a concerning review they may be subject to an investigation at the discretion of the QPDD.

(3) Investigations will be conducted by the QPDD.

16 Suspension of QMP Licence

(1) A QMP Licence is suspended if a licenced prescriber is -

(a) Inactive for a period of 18 months; or

(b) The subject of a serious QPDD investigation.

(2) A QMP licence is revoked if -

(a) A patient suffers severe health consequences as a result of MDMA misuse including -

(i) Death;

(ii) Permanent disablement; and/or

(iii) Severe medical emergencies.

(b) A QPDD investigation finds the licenced prescriber was negligent in their treatment of a patient.

(3) Licenced prescribers who have their QMP licences revoked are permanently ineligible to reapply.

(4) Licenced prescribers who have their QMP license suspended are eligible to reapply.

Part 5 Eligibility Criteria

17 Extent of Eligibility Criteria

(1) The eligibility criteria must be met in order to be deemed eligible for -

(a) Medical trials involving MDMA; or

(b) Prescription of MDMA by a licenced prescriber.

(2) If the eligibility criteria are not met, patients become permanently ineligible for any future medical trials.

(3) Patients may reapply for clinical use eligibility once every 18 months from initial application.

18 Eligibility Criteria

(1) To be deemed fit for consideration, a person must be-

(a) At least 18 years or older;

(b) Clinically assessed by a licenced prescriber as having a CAPS-IV score greater than 84.0;

(c) Clinically assessed by a health professional with relevant qualifications as being in a state of physical health such that prescription of MDMA is unlikely to have serious consequences for the patient's health and safety;

(d) Free from any medical contraindications for receiving MDMA.

(2) To be deemed eligible patients must -

(a) Be fit for consideration;

(b) Have undertaken with a licenced prescriber -

(i) A minimum of 24 sessions therapy sessions;

(A) Of sixty minutes or longer;

(B) At least once every fortnight; and

(C) For a minimum of six months.

(c) Have been unresponsive to at least one course of -

(i) Pharmacotherapy; or

(ii) Unassisted psychotherapy;

(d) Be fluent in speaking and reading the predominantly used or recognised language of the treatment facility, unless an interpreter can be provided and all relevant

written materials are available to the patient in their own language;

(e) Agree to have study visits recorded, including Experimental Sessions, Independent Rater assessments, and non-drug psychotherapy sessions.

19 Exclusion Criteria

(1) A patient may not be deemed eligible if they:

(a) Are under the age of 18;

(b) Are unable to give adequate informed consent;

(c) Have evidence or history of significant medical disorders that could render the prescription of MDMA unsafe, including uncontrolled hypertension, heart failure, hypokalemia, symptomatic liver disease, hyponatremia or hyperthermia;

(d) Weigh less than 48 kilograms (kg);

(e) Are pregnant or nursing;

(f) Are abusing illegal drugs;

(g) Have a history of -

(i) Illegal drug abuse; or

(ii) Involvement in the illegal manufacture or distribution of illegal drugs; or

(iii) Involvement with organised crime.

Part 6 Treatment Phase

20 Main objectives of this part

(1) Create treatment procedures to ensure high quality treatment.

(2) Stipulate MDMA dosages to ensure patient safety.

(3) Establish consequences for not following treatment procedures and relevant protocols.

21 Preliminary

(1) This part applies whenever MDMA is prescribed in the context of -

(a) Medical trials for research and development purposes;

(b) Clinical use by licenced prescribers.

(2) Only a licensed prescriber may prescribe MDMA under this Youth Act.

(3) At any one time there is to be only one licensed prescriber responsible for administering MDMA to a particular patient.

(4) MDMA may only be prescribed to an eligible patient.

(5) MDMA may be administered under this Youth Act only in accordance with a prescription made under this Youth Act.

(6) MDMA may only be prescribed to a person who has commenced the treatment process, and may only be administered during the treatment process.

(7) The treatment process is considered to have commenced when the patient is prescribed MDMA for the purposes of the treatment process, and to end when the licensed prescriber responsible for prescribing MDMA to the patient considers the treatment process to be completed; but not within 24 hours of the last time that the patient was administered MDMA under the treatment process.

(8) A patient undertaking the treatment process must remain supervised by an authorised person at all times and may only leave the treatment facility accompanied by an authorised person.

(9) MDMA may not be prescribed to a person who has, or is believed by the Prescriber to have,

(a) Drunk alcohol or caffeine for at least 72 hours;

(b) Used illicit substances within the last week.

(10) After being admitted to the treatment facility and before being prescribed MDMA, a patient must be introduced to all relevant administrators and health professionals.

22 Treatment Guidelines

(1) Once the QPDD authorises clinical use of MDMA following the initial research phase, the QPDD must introduce mandatory guidelines regulating the treatment process, that must be applied in all clinical use of MDMA.

(2) In developing such guidelines, the QPDD must take into account all relevant factors, including the results of the research conducted in the initial research phase; and the QPDD must update the guidelines at its discretion as new research becomes available.

23 MDMA Dosages

(1) In determining the amount of MDMA to prescribe to a patient for use at a particular time, the Prescriber must take into account:

(a) The patient's

(i) Health;

(ii) Gender;

(iii) Weight;

(iv) Age;

(v) Psychological state; and

(vi) Medical history; and

(b) How long it has been since the patient last took MDMA, whether as part of the treatment process or otherwise;

(c) The research findings produced under this Youth Act and any other relevant research; and

(d) Any other relevant factors.

(2) Despite subsection (1), a dose exceeding 120 mg of MDMA may not be prescribed, and the total amount of MDMA administered within any 24-hour period must not exceed 120 mg.

(3) Patients are unable to request alterations to their dosage.

24 Post Treatment Protocols

(1) On the completion of the treatment process, patients are to be discharged from the treatment facility, but must not for 72 hours since the last does of MDMA was administered

(a) Operate heavy machinery (drive);

(b) Make legally binding decisions;

(c) Consume -

(i) Alcohol; or

(ii) Caffeine

(2) For two weeks post treatment patients must -

(a) Be physically active daily for at least 20 minutes or;

(b) Undertake 20 minutes of meditation/mindfulness daily.

(3) A patient must complete any tasks and/or activities set by the Prescriber.

(4) A patient may not be discharged under subsection (1) if the Prescriber considers that the patient is likely to

(a) Take illicit substances within 72 hours; or

(b) Pose a risk to the health or safety or any person, including the patient.

25 Consequences for not following clinical trial procedures

(1) Patients undergoing the treatment process who intentionally disobey protocols and instructions provided to them by an authorised person (a violation) will face verbal warning from trial administrators.

(2) If a violation under subsection (1) is considered by the Prescriber to be a serious violation involving a risk to the health or safety of any person, the Prescriber may exercise their discretion to suspend the patient temporarily from the treatment process and place the patient in the post-treatment phase described in s 23, but most not release the patient within 72 hours of the last dose of MDMA being administered.

(3) If the Prescriber considers it vital as a matter of health and safety that the patient not continue with the treatment process, whether as a result of serious violations or otherwise; the Prescriber may place the patient directly in the post-treatment phase, in which case the patient will be deemed ineligible to reapply for treatment at any later time.

(4) A violation involving the use of prescribed MDMA by the patient to harm any person including the patient will also be dealt with under the *Drugs Misuse Act 1986* (Qld), but the QPDD has discretion to disallow, in consultation with the Attorney-General, any prosecution of the patient for a violation if the QPDD considers that the effects of the MDMA prescribed under the treatment process were a substantial cause of the violation.

(5) If the Prescriber believes it is unsafe to release the patient after 72 hours have elapsed since the last dose of MDMA is administered, the patient may be detained at the facility until the QPDD decides whether to seek a court order or release the patient. A court order may be sought from the Queensland Supreme Court, which will have full discretion to detain the patient or release the patient either with or without any restrictions or requirements that the Supreme Court deems fit to impose.

Part 7 Research and Development Phase

26 Main objectives of this part

(1) To decide the institutions which will conduct the research.

(2) Outline the research process of MDMA-assisted therapy on humans.

(3) Decide where MDMA clinical trials will occur for testing.

27 Institution Delegation for MDMA research and development

(1) Research into MDMA-assisted therapy will be conducted by:

(a) Universities within Queensland; or

(b) Private clinical companies; and

(c) Government backed medical research institutions within Queensland.

(2) Cross institutional collaboration and research with medical institutions across other Australian states is allowed, but international collaboration is prohibited.

28 Clinical Trials

(1) To conduct MDMA research, clinical trials must be initiated to -

(a) Reduce negative neuropsychological responses and thoughts about one self;

(b) Increase insight into personal problems;

(c) Expand mental perspectives of clients;

(d) Influence positive changes in terms of attitude and feelings of oneself; and

(e) Decrease the risk of harm to others

(2) To commence clinical trials, preparations must be made to -

(a) Gather informed consent of participating clients.

(b) Perform screening procedures for -

(i) Severe Combined Immunodeficiency (SCID);

(ii) CAPS-IV;

(iii) Neuropsychological measures;

(iv) Physical examination;

(v) Blood tests; and

(vi) Electrocardiogram tests (EKG)

(c) Prepare and perform three 90 minute sessions alongside an experienced co-therapy team.

(3) After clinical trial sessions, post screening protocols must be made to -

(a) Re-perform screening procedures to monitor patients progress and responses to treatment.

(b) Communicate feedback with patients on their behaviour during the trial sessions, schedule the next meeting for patients.

(4) MDMA may not be prescribed to animals under this Youth Act either for research or clinical purposes.

29 Locations Suitable for MDMA-assisted clinical trials

To conduct MDMA-assisted clinical trials, facilities deemed suitable for testing are:

(a) Hospitals -

(i) Can occur in regional and urban areas;

(ii) Sessions must be located in areas so as to not interfere with daily hospital schedule and maintenance;

(iii) Must occur in rooms isolated from reception and operation rooms;

(iv) Rooms used for trials must abide by health and safety regulations;

(v) Prohibit entrance of individuals who are not authorised or called to conduct the trials; and

(vi) Clinics must have a structured pre and post screening room built or set up for visiting patients.

(b) Private and government clinics -

(i) Rooms used for trials must abide by health and safety regulations;

(ii) Trials sessions will only be attended to by authorised and qualified attendants;

(iii) Clinics must have a structured pre and post screening room built or set up for visiting patients; and

(iv) Have nearby readily accessible food, preferably snacks with low sugar content, and water.

Part 8 Clinical Use

30 Main Objectives

(1) The main objectives of this part are to -

(a) Create a safe environment for patients undergoing MDMA treatment;

(b) Ensure quality procedures to maximise effectiveness; and

(c) Support patients post treatment to improve and monitor recovery.

(2) This Part utilises the treatment plan and procedures outlined in Part 6.

31 Available for Clinical Use

Once MDMA-assisted psychotherapy treatment has passed medical trials, it will become immediately available for clinical use meaning -

(a) Licenced prescribers will be able to prescribe treatment to eligible patients;

(b) Facilities may accept bookings for treatment; and

(c) Manufacturers may sign a non-beneficiary contract

32 Locations Suitable for Treatment

Clinical use of MDMA-assisted psychotherapy must be undergone in -

(a) Hospitals which -

(i) Are publicly owned;

(ii) Have sufficient staffing to ensure constant direct supervision at a 1:1 ratio;

(iii) Provide private rooms for patients;

(iv) Have secure drug storage facilities to safely store the MDMA; and

(v) Prohibit the entrance of individuals who are not authorised to treat the patient.

33 Post Treatment Testing

In addition to the post treatment protocols outlined in 23(7), patients will be subject to -

(a) CAPS-IV testing 1 week post treatment;

(b) Additional counseling by -

(i) The licenced prescriber; or

(ii) A licenced mental health specialist.