

POISONS (PSYCHOTROPIC SUBSTANCES) REGULATIONS 1989
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Preamble

IN exercise of the powers conferred by section 30 of the Poisons Ordinance 1952 [29/52], the Minister makes the following regulations :

Regulation 1. Citation and commencement.

These Regulations may be cited as the **Poisons (Psychotropic Substances) Regulations 1989** and shall come into force on the 15th April 1989.

Regulation 2. Interpretation.

In these Regulations, unless the context otherwise requires -

"competent authority" means the national authorities empowered to issue certificates and authorisations recognised by the Government of Malaysia, for the import and export of psychotropic substances;

"Convention" means the Convention on Psychotropic Substances that was adopted for signature at Vienna on the 21st February 1971;

"export" , with its grammatical variations and cognate expressions, means to take or cause to be taken out of Malaysia by land, air or water, otherwise than in transit;

"import", with its grammatical variations and cognate expressions, means to bring or cause to be brought into Malaysia by land, air or water, otherwise than in transit;

"in transit" means taken or sent from any country and brought into Malaysia by land, air or water, whether or not landed or transhipped in Malaysia, for the sole purpose of being carried to another country either by the same or another conveyance;

"name of the psychotropic substance" means the International Non-proprietary Name (INN) of the psychotropic substance or, in the absence of the INN, the chemical name of the psychotropic substance;

"Ordinance" means the Poisons Ordinance 1952;

"senior officer of Customs" shall have the meaning assigned to it in the Customs Act 1967 [Act 235].

Regulation 3. Prohibition on possession of psychotropic substance.

(1) No person shall have in his possession any psychotropic substance unless -

(a) he is authorised to be in possession of such psychotropic substance under these Regulations;
and

(b) the psychotropic substance in his possession is -

(i) for a lawful purpose; and

(ii) obtained in accordance with the provisions of these Regulations.

(2) For the purposes of paragraph (a) of subregulation (1), the following persons or class of persons shall be authorised to be in possession of psychotropic substance:

(a) a licenced pharmacist;

(b) a registered medical practitioner;

(c) a registered dentist Division I;

(d) a veterinary surgeon;

(e) the holder of a permit issued under regulation 15;

(f) a person employed in any hospital at which human ailments are treated and for the time being in charge of any ward, operating theatre or of other sections of such hospital who possesses psychotropic substance for use in such ward, operating theatre or sections;

(g) a person concerned with scientific education or research or chemical analysis in a department, university or institution wholly maintained by the Government or approved by the Director General of Health;

(h) a pharmacist in the public service;

(i) an officer of Customs, police officer or an officer of the Postal Department when acting in the course of his duty as such;

(j) a Drug Enforcement Officer;

(k) a person engaged in the delivery of any psychotropic substance from a lawful supplier to a person authorised to have it in his possession, for such period as in the circumstances of the case is reasonably sufficient to enable the delivery to the recipient to be effected;

(l) a person lawfully supplied with such psychotropic substance--

(i) by a registered medical practitioner, registered dentist Division I or a veterinary surgeon; or

(ii) in accordance with a prescription lawfully given by a registered medical practitioner, registered dentist Division I or a veterinary surgeon;

(m) a person acting on behalf of the class of the persons mentioned in paragraph (l);

(n) a person possessing psychotropic substance for administration to a patient or animal in accordance with the direction of a registered medical practitioner, registered dentist Division I or a veterinary surgeon, as the case may be.

Regulation 4. Control of import and export of psychotropic substance.

(1) Except as otherwise provided in these Regulations, no person shall import or export any psychotropic substance unless--

(a) he has in his possession a valid and subsisting import or export authorisation, as the case may be, relating to such psychotropic substance; and

(b) such import or export is in accordance with the terms and conditions specified in the import or

export authorisation relating thereto.

(2) The provisions of subregulation (1) shall not apply to -

(a) any person arriving in or leaving Malaysia who carries as part of his personal luggage and solely for his personal use or for the use of his family, a prepared or packaged medicine containing any psychotropic substance, not exceeding such quantities as may be reasonably required for one month's use by one person, which has been lawfully supplied to such person by or on the prescription of a qualified medical practitioner; or

(b) the international carriage by ships, aircrafts or other forms of international public transport entering or leaving Malaysia of such limited quantities of any psychotropic substance as may be required during their journey or voyage for first aid purposes or emergency cases.

Regulation 5. Application for an import authorisation.

(1) An application for an import authorisation in respect of any psychotropic substance shall be made to the Licensing Officer in Form A in the First Schedule.

(2) Upon receipt of an application under subregulation (1), the Licensing Officer may in his discretion issue an import authorisation in Form B in the First Schedule subject to such terms and conditions as may be imposed by such Licensing Officer.

(3) The Licensing Officer shall prepare the import authorisation in triplicate and shall--

(a) issue two copies to the intending importer who shall forward one copy thereof to the person from whom the psychotropic substance is to be obtained; and

(b) send the third copy direct to the competent authority of the country from which the psychotropic substance is to be imported.

Regulation 6. Application for an export authorisation.

(1) An application for an export authorisation in respect of any psychotropic substance shall be made to the Licensing Officer in Form A in the First Schedule.

(2) Upon receipt of an application under subregulation (1), the Licensing Officer may, upon the production of an import authorisation or an approval of import certificate duly issued by the competent authority of the country to which the psychotropic substance is to be exported, in his discretion issue an export authorisation in Form C in the First Schedule subject to such terms and conditions as may be imposed by such Licensing Officer.

(3) The Licensing Officer shall prepare the export authorisation in triplicate and shall -

(a) issue two copies to the exporter who shall send one copy with the psychotropic substance to which it refers when such psychotropic substance is exported; and

(b) send the third copy direct to the competent authority of the country into which the psychotropic substance is to be exported.

Regulation 7. Fee for import or export authorisation.

(1) Every application for an import or export authorisation shall be accompanied by a fee of two hundred ringgit.

(2) The fee which has been paid under subregulation (1) shall not be refundable.

[Subs. P.U.(A) 405/2018]

Regulation 8. Furnishing of information to Drug Enforcement Officer, etc.

At the time of importation or exportation of any psychotropic substance, the importer or exporter shall produce to a Drug Enforcement Officer or any proper officer of Customs the import or export authorisation relating thereto, and such other evidence as such officer may require to satisfy him that the psychotropic substance is being imported or exported lawfully and in accordance with the terms and conditions of such authorisations.

Regulation 9. Import or transit of psychotropic substance specified in the Second Schedule.

Every psychotropic substance specified in the Second Schedule which is imported into Malaysia, or brought to Malaysia in transit, from a country which is a party to the Convention shall be accompanied by a valid and subsisting export authorisation duly issued by the competent authority of the country from which it is exported; and the person having the possession or control of such psychotropic substance shall, on demand by any Drug Enforcement Officer, any police officer not below the rank of Inspector or any senior officer of Customs, produce such export authorisation for his inspection.

Regulation 10. Control of psychotropic substance in transit.

No psychotropic substance while in transit shall be subjected to any process which would change the nature of such psychotropic substance and the packing shall not be altered without the written consent of the Licensing Officer.

PART IV

SALE AND SUPPLY OF PSYCHOTROPIC SUBSTANCE

Regulation 11. Control on the sale and supply of psychotropic substance for medical or dental treatment of a particular patient or animal treatment of a particular animal.

(1) No psychotropic substance shall be sold or supplied for the purposes of medical or dental treatment of a particular patient or animal treatment of a particular animal except by -

(a) a registered medical practitioner for the purposes of the medical treatment of his patient only;

(b) a registered dentist Division I for the purposes of the dental treatment of his patient only;

(c) a veterinary surgeon to his client for the purposes of animal treatment only;

(d) a licensed pharmacist upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I or a veterinary surgeon;

(e) a pharmacist who is for the time being employed in a hospital, clinic or dispensary wholly maintained by the Government, or in an institution approved by the Director General of Health at which human ailments are treated, upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I or a veterinary surgeon;

(f) any of the persons mentioned in paragraphs (a) to (e) of this regulation and paragraph (f) of subregulation (2) of regulation 3 to a person authorised to administer psychotropic substance, upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I or a veterinary surgeon.

(2) Every prescription for any psychotropic substance prescribed by a registered medical practitioner, registered dentist Division I, or veterinary surgeon shall -

(a) be in writing, signed and dated by the prescriber thereof;

(b) state the full name, address and telephone number of the prescriber;

(c) state the age, full name and address of the patient or, in the case of a prescription by a veterinary surgeon, the full name and address of the person to whom such psychotropic substance is to be delivered;

(d) indicate the total amount of psychotropic substance to be supplied and the dose; and

(e) specify the number of times (not exceeding three) the psychotropic substance may be supplied and, if supplied more than once, at what intervals.

(3) No person shall sell or supply any psychotropic substance on a prescription -

(a) which does not comply with all the requirements of subregulation (2);

(b) which contravenes the provisions of subregulation (5);

(c) otherwise than in accordance with the terms of such prescription; or

(d) which is presented to him more than ninety days after date of the prescription.

(4) Every person selling or supplying any psychotropic substance on a prescription shall, at the time of selling or supplying the same, endorse upon the face of the prescription above the signature of the prescriber, his name and address and the date on which such psychotropic substance was sold or supplied.

(5) No prescription for any psychotropic substance shall be written wholly or partly in code or in such manner that it is not readily decipherable and capable of being dispensed by any pharmacist.

(6) Notwithstanding any provisions to the contrary, if it shall appear to the seller or supplier that any psychotropic substance is required urgently in cases of emergency and that it is impossible without unreasonable delay to obtain a prescription complying with the requirements of paragraph (d) or (e) of subregulation (1), it shall be lawful for the seller or supplier, after making an entry to that effect in his prescription register for psychotropic substance, upon the verbal or telephoned instructions of a registered medical practitioner, registered dentist Division I or veterinary surgeon, personally known to him, to sell or supply such psychotropic substance without a prescription:

Provided that in every such case the seller or supplier --

(a) shall take all necessary steps to obtain, and the prescriber shall deliver, a prescription as required in paragraph (d) or (e) of subregulation (1) within one day of the date of such sale or

supply;

(b) shall not sell or supply more than one day's supply of such psychotropic substance; and

(c) shall take such reasonable steps to ascertain the authenticity of the person who gave the instructions.

(7) Every prescription for the sale or supply of psychotropic substance shall be kept for a period of at least two years from the date of sale or supply.

Regulation 12. Control on the sale and supply of psychotropic substance for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal.

(1) Subject to subregulation (2), no psychotropic substance shall be sold or supplied for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal except by a licensed pharmacist or a pharmacist in the public service to--

(a) another licensed pharmacist or pharmacist in the public service;

(b) subject to regulation 12A, a registered medical practitioner, registered dentist Division I or veterinary surgeon;

[(b) Subs. P.U.(A) 10/2011]

(c) a person concerned with scientific education or research or chemical analysis in a department, university or institution wholly maintained by the Government or approved by the Director General of Health;

(d) a person holding a valid and subsisting permit to purchase and use psychotropic substance issued under regulation 15; or

(e) subject to regulation 4, a purchaser outside Malaysia.

(2) Any person who sells or supplies psychotropic substance--

(a) as commercial sample shall be required to have a valid clinical trial import licence issued under the Control of Drugs and Cosmetics Regulation 1984 *[P.U.(A) 223/84]*, for such psychotropic substance;

(b) to a person in Malaysia, in such quantity and at such frequency that appears to be not reasonably required by such person acting in the ordinary course of his profession, function or employment shall be required to obtain -

(i) such person's signature in the supply register or a signed written order; and

(ii) a written attestation from such person relating to his requirement for such psychotropic substance in such quantity and at such frequency, as the case may be,

before any sale or supply is made.

Regulation 12A. Sale and supply of buprenorphine and methadone to registered medical practitioner, etc.

A licensed pharmacist or a pharmacist in the public service shall not sell or supply buprenorphine and methadone to a registered medical practitioner, registered dentist Division I or veterinary surgeon for purposes other than the medical or dental treatment of a particular patient or animal treatment of a particular animal, as the case may be, unless a permit to purchase and use psychotropic substance under regulation 15 has been issued to the registered medical practitioner, registered dentist Division I or veterinary surgeon.

[Ins.P.U.(A) 10/2011]

Regulation 13. Exemption from regulation 12(1).

The provisions of subregulation (1) of regulation 12 shall not apply -

(a) to the sale or supply of psychotropic substances by a licensed pharmacist or a registered pharmacist in the public service, or, in the absence of such person, a registered medical practitioner, who is employed in any hospital, and who sells or supplies within the same hospital such psychotropic substance to the person, and for the purposes, specified in paragraph (f) of subregulation (2) regulation 3; or

(b) to a case where the psychotropic substance is to be returned to the original supplier within Malaysia who supplied the psychotropic substance in the first instance; provided that such a transaction is noted in the relevant register for psychotropic substance and an official acknowledgement of receipt from such supplier is kept.

Regulation 14. Issue of permit to purchase and use psychotropic substance.

(1) For the purposes of these Regulations, a permit to purchase and use psychotropic substance shall only be issued to -

(a) a professional person or tradesman for the purpose of such person's or tradesman's profession or trade only; or

(b) a game warden or a person assigned to act as a game warden by the relevant authority for such game warden's or person's use on animals only.

(2) Notwithstanding subregulation (1), a permit to purchase and use psychotropic substance shall be issued to a registered medical practitioner, a registered dentist Division I or a veterinary surgeon relating to buprenorphine and methadone for the purpose as may be specified by the Licensing Officer in the permit.

[(2) Ins. P.U.(A) 10/2011]

Regulation 15. Application for a permit to purchase and use psychotropic substance.

(1) An application for a permit to purchase and use psychotropic substance shall be made in Form D in the Third Schedule to the Licensing Officer who may in his discretion issue such a permit or reject the application.

(2) A permit to purchase and use psychotropic substance shall be in Form E in the Third Schedule and shall be valid for a specified period not exceeding twelve months.

(3) The Licensing Officer may in issuing a permit under this regulation impose such terms and conditions as he thinks fit, and may from time to time vary the terms and conditions so imposed.

(4) Every application for a permit to purchase and use psychotropic substance shall be accompanied by a fee of three hundred ringgit.

[(4) Subs. P.U.(A) 405/2018]

(4A) The fee which has been paid under subregulation (4) shall not be refundable.

(5) The Licensing Officer may cancel any permit issued under this regulation, if he is satisfied that -

(a) the holder of the permit has contravened any provisions of these Regulations or any terms and conditions imposed by the Licensing Officer; or

(b) the holder of the permit has furnished false, misleading or inaccurate information, or has concealed or failed to disclose material facts, in his application for such permit.

(6) The Licensing Officer shall, before cancelling any permit under subregulation (5), cause to be given to the holder of such permit a notice in writing of his intention to do so and calling the person concerned to show cause why his permit should not be cancelled.

(7) Any person aggrieved by the refusal of the Licensing Officer to issue a permit under subregulation (1), or by the cancellation of any permit under subregulation (5), may appeal in writing to the Minister against such refusal or cancellation within a period of thirty days after the date of such refusal or cancellation.

(8) The Minister may, after hearing the appeal, make such order as he deems fit and that order shall be final.

Regulation 16. Control of administration of psychotropic substance.

No person shall administer any psychotropic substance unless he is -

(a) a registered medical practitioner;

(b) a registered dentist Division I;

(c) a veterinary surgeon; or

(d) a person acting in accordance with the direction of a registered medical practitioner, registered dentist Division I or a veterinary surgeon, and the psychotropic substance is administered for the purpose of medical or dental treatment of a particular patient or animal treatment of a particular animal.

Regulation 17. Control of dispensing, etc. of psychotropic substance.

No person shall dispense, compound or mix any psychotropic substance with any other substance, whether a psychotropic substance or not, for the purpose of it being used for medical, dental or animal treatment unless he is -

(a) a licensed pharmacist; or

(b) a pharmacist in the public service.

Regulation 18. Control of manufacture of psychotropic substance.

No person shall manufacture any psychotropic substance unless he is a licensed pharmacist or a pharmacist in the public service or a person working under the immediate personal supervision of a licensed pharmacist or a pharmacist in the public service :

Provided that where in the process of manufacture, any weighing or measuring of any

psychotropic substance or any mixing of any psychotropic substance with any other substances is required to be done under the immediate personal supervision of such person, it shall not be deemed to have been done unless such person has himself checked and endorsed in writing such weighing, measuring or mixing

Regulation 19. Records for purposes of medical, dental or animal treatment.

Any person who sells or supplies or administers any psychotropic substance for the purposes of medical or dental treatment of a particular patient or animal treatment of a particular animal shall keep and maintain a register to be called the "Prescription Register For Psychotropic Substance", and shall, on the day such psychotropic substance is sold or supplied or administered, enter or cause to be entered therein true particulars with respect to --

[Am. P.U.(A) 19/99]

(a) the date on which the psychotropic substance was sold or supplied or administered and the serial number of the entry in such register;

[Am. P.U.(A) 19/99]

(b) the name and strength of the psychotropic substance and the quantity sold or supplied or administered;

[Am. P.U.(A) 19/99]

(c) the name, identity card number, passport number or any other legal identification document and address of the patient, or where the prescriber is a veterinary surgeon or the prescription relates to animal treatment, the name and address of the recipient:

[(c) Am. P.U.(A) 221/2013]

Provided that where such sale or supply is made upon a prescription which is repeated it shall be sufficient to enter in the prescription register for psychotropic substance the quantity of the psychotropic substance sold or supplied, the date and the serial number of the sale or supply originally entered.

[Am. P.U.(A) 19/99]

Regulation 20. Records for purposes other than medical, dental or animal treatment.

Any person who sells or supplies any psychotropic substance for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal shall keep and maintain a register to be called the "Supply Register for Psychotropic Substance", and shall not deliver such psychotropic substance until -

(a) he has entered or cause to be entered in such register true particulars with respect to the full name and address of the prospective purchaser or recipient, the date of the sale or supply, the name, strength and quantity of the psychotropic substance sold or supplied and the purposes for which it is stated to be required; and

(b) the prospective purchaser or recipient has affixed his signature to the entry or has forwarded to the seller or supplier a written order in respect of such sale or supply signed by such person and containing the particulars required to be entered under paragraph (a). Every such written order shall be retained by the seller or supplier and a reference to the file in which such order is retained shall be entered in the supply register for psychotropic substance in place of the

prospective purchaser's or recipient's signature.

Regulation 21. Records of manufacture of psychotropic substance.

Any person who manufactures any psychotropic substance shall keep and maintain a register to be called the "Production Register For Psychotropic Substance", and shall enter therein true particulars with respect to -

- (a) the date of which the psychotropic substance was used for manufacture and the amount used;
- (b) the pharmaceutical dosage form of the psychotropic substance manufactured and the quantity of psychotropic substance found in each unit of the pharmaceutical dosage form;
- (c) the theoretical yield of the psychotropic substance in pharmaceutical dosage form manufactured and the batch number assigned to it;
- (d) the actual yield of the psychotropic substance in pharmaceutical dosage form manufactured;
- (e) the total units of the psychotropic substance in pharmaceutical dosage form sampled for the purpose of quality control; and
- (f) the total units of the psychotropic substance in pharmaceutical dosage form transferred for the purpose of sale or supply.

Regulation 21A. Records of psychotropic substance received, administered or delivered.

The person authorised to be in possession of psychotropic substance referred to in paragraphs 3(2)(a) to (f), (h) and (k) shall keep and maintain a register to be called the "Register of Psychotropic Substance Received, Delivered or Administered."

[Ins. P.U.(A) 10/2011]

Regulation 22. Keeping and maintenance of register.

Every person who is required to keep and maintain any register under these Regulation -

- (a) shall use a separate register or a separate part of the register with respect to each type of psychotropic substance;
- (b) shall enter in the register every quantity of psychotropic substance received, delivered or administered, as the case may be, by him whether for the purpose of sale, supply, administration or any other purpose, the total stock of such psychotropic substance in his possession, the name and address of the supplier or the recipient of such psychotropic substance, and the date on which such psychotropic substance was received, delivered or administered by him or the reference number of the patient or client such psychotropic substance was administered to.

[(b) Subs. P.U.(A) 10/2011]

- (c) shall not make any cancellation, obliteration or alteration of an entry in any register, and any correction of an entry must be made by way of a marginal note or a footnote which must specify the date on which the correction is made;

(d) shall make the required entry in chronological order with respect to the previous entries in the register;

(e) shall keep the register on the premises to which the register relates to the sale, supply or manufacture or administration of any psychotropic substance in such premises.

[Am. P.U.(A) 19/99]

Regulation 23. Form of register.

Every register required under these Regulations shall -

(a) be in the form of a bound book or in the form which has the written approval of the Licensing Officer subject to the terms and conditions as he may impose; and

[(a) Am. P.U.(A) 221/2013]

(b) be preserved for a period of two years from the date of the last entry in such register.

Regulation 24. Control of storage of psychotropic substance.

(1) Any person who possesses any psychotropic substance for the purposes of manufacturing, dispensing, compounding, mixing, sale, supply, education, research or chemical analysis, shall store such psychotropic substance in a room, cabinet, safe or receptacle which shall remain locked except in so far as may be necessary to have such room, cabinet, safe or receptacle opened in order to--

(a) carry out the purposes described above in connection with the psychotropic substance stored therein;

(b) keep other psychotropic substance in such room, cabinet, safe or receptacle; or

(c) conduct a stock check of the psychotropic substance stored therein.

(2) Any room, cabinet, safe or receptacle used to store any psychotropic substance--

(a) shall be placed on the premises to which such psychotropic substance relates to the manufacturing, dispensing, compounding, mixing, sale, supply, education, research or chemical analysis only; and

(b) shall be locked and unlocked by the person authorised to possess such psychotropic substance, and the keys to such room, cabinet, safe or receptacle shall be kept by him only.

[(2) Subs.P.U.(A) 221/2013]

(3) For the purposes of this regulation, any room, cabinet, safe or receptacle used for storing any psychotropic substance shall be so constructed and with reasonably sufficient security measures in order to prevent theft or diversion of the psychotropic substance stored therein.

Regulation 25. Control on disposal of psychotropic substance.

(1) No person who is required to keep and maintain a register under regulation 19, 20 or 21 shall dispose of the psychotropic substance in his possession except in the presence and in accordance with the instructions of a Drug Enforcement Officer.

(2) True particulars of the date of disposal and the quantity of the psychotropic substance which is disposed of shall be entered in the register to which it relates and shall be acknowledged by the Drug Enforcement Officer.

(3) The Drug Enforcement Officer may, for the purpose of analysis, demand, take or obtain a sample of any psychotropic substance which is to be disposed of.

(4) For the purposes of this regulation, "dispose of" and its grammatical variations, in relation to psychotropic substance, mean to bury, burn or otherwise render in a manner with no or negligible risk of recovery.

Regulation 26. Control on labelling of psychotropic substance.

(1) Except as otherwise provided in these Regulations, no person shall keep, have in his possession or under his control, any psychotropic substance otherwise than in a container labelled, in a conspicuous position thereon and in a clear and distinct manner, with--

(a) the name of the psychotropic substance; and

(b) the word "Poison" in Bahasa Malaysia, English, Chinese and Tamil printed in red or in a red background :

Provided that the requirement of paragraph (b) of this regulation shall not apply to a container which is enclosed in an unbroken case or package as received from the manufacturer of the psychotropic substance outside Malaysia.

(2) Where any container of any psychotropic substance is enclosed in a box or covering, such box or covering shall be labelled in the same manner as the container :

Provided that nothing in this subregulation shall make it necessary to label any transparent cover or wrapper, or any hamper, packing case, crate or other covering used solely for the purpose of transportation or delivery.

(3) The requirement of paragraph (b) of subregulation (1) shall not apply to any psychotropic substance contained in an ampoule, cachet or similar article, if every box or other covering in which the ampoule, cachet or article is enclosed is duly labelled.

(4) Nothing in this regulation shall apply to any psychotropic substance kept or possessed by, or under the control of, a person in the case where such psychotropic substance was sold or supplied to him by or upon a prescription prescribed by a registered medical practitioner, registered dentist Division I or veterinary surgeon for medical, dental or animal treatment.

Regulation 27. Labelling requirements for purposes other than medical, dental or animal treatment.

No person shall sell or supply any psychotropic substance for purposes other than medical or dental treatment of a particular patient or animal treatment of a particular animal unless the container of such psychotropic substance is labelled conspicuously and distinctly -

- (a) in the manner specified in subregulation (1) of regulation 26;
- (b) in the case of a medicine which contains psychotropic substance as one of the ingredients thereof -
 - (i) with the particulars of the proportion in which the psychotropic substance contained in such medicine bears to the total ingredients;
 - (ii) with the warning "Caution: This preparation may be habit forming on prolonged use"; and
- (c) with the name of the seller or supplier and the address of the premises on which it was sold or supplied:

Provided that this requirement does not apply in the case of a container which had been labelled with the name of the seller or supplier and the address of the premises on which it was previously sold or supplied.

Regulation 28. Labelling requirement for purposes of medical, dental or animal treatment.

Where any psychotropic substance is sold or supplied for the purpose of medical or dental treatment of a particular patient or animal treatment of a particular animal, the container of such psychotropic substance shall be labelled in a conspicuous and distinct manner with -

- (a) the full name and address of the seller or supplier;
- (b) the full name of the patient or purchaser;
- (c) adequate directions for the use of such psychotropic substance;
- (d) the date when such psychotropic substance was sold or supplied; and
- (e) the name and strength of the psychotropic substance.

Regulation 29. Order prohibiting possession, sale, supply, etc. of psychotropic substances.

(1) Where -

- (a) a person who is a registered pharmacist, registered medical practitioner, registered dentist Division I or veterinary surgeon has been convicted of an offence relating to psychotropic substances under the Ordinance or these Regulations; or
- (b) the Minister has reasonable ground to believe that a person who is a registered medical practitioner, registered dentist Division I or a veterinary surgeon is prescribing, administering or supplying or directing the administration of psychotropic substances in an irresponsible manner,

the Minister may, subject to and in accordance with regulation 30, make an order under subregulation (2) in respect of that person.

(2) An order under this subregulation in respect of any person shall be an order -

- (a) if that person is a registered pharmacist, prohibiting him from having in his possession, selling,

supplying, manufacturing, compounding, mixing, dispensing and supervising the manufacture of such psychotropic substances as may be specified in the order;

(b) if that person is a registered medical practitioner, prohibiting him from having in his possession, selling, supplying, prescribing, dispensing, mixing, administering and from directing the administration of such psychotropic substances as may be specified in the order;

(c) if that person is a registered dentist Division I or a veterinary surgeon, prohibiting him from having in his possession, selling, supplying, prescribing, administering and from directing the administration of such psychotropic substances as may be specified in the order.

Regulation 30. Procedure before making an order under regulation 29(2).

(1) Before making an order under subregulation (2) of regulation 29, the Minister shall serve or cause to be served on the person against whom the order is proposed to be made a written notice informing him of -

(a) the terms of the proposed order;

(b) the ground on which the proposed order is to be made; and

(c) his right to make a written representation to the Minister within the period of thirty days beginning with the date of the service of the notice.

(2) If any such representations are received by the Minister within the period aforesaid, he shall refer the case to the relevant advisory committee constituted in accordance with the following provisions of these Regulations; and it shall be the duty of the advisory committee to consider the case and to advise the Minister as to the exercise of his power under subregulation (3).

(3) After the expiration of the period of thirty days and, in the case of a reference to an advisory committee under subregulation (2), after considering the advice of that committee, the Minister may -

(a) make in respect of such person the relevant order under subregulation (2) of regulation 29; or

(b) order that no further proceedings under this regulation shall be taken in the case.

Regulation 31. Provisions supplementary to regulations 29 and 30.

(1) The provisions of the Fourth Schedule shall have effect with respect to the constitution and procedure of any advisory committee appointed for the purpose of regulation 30.

(2) The Minister shall cause a copy of any order made by him under subregulation (2) of regulation 29 to be served on the person to whom it applies and notice of it to be published in the *Gazette*.

(3) The Minister may by order cancel or suspend any order made by him under subregulation (2) of regulation 29 or cancel any order of his under this subregulation by which the order so made is suspended.

(4) Any order made under subregulation (3), or under subregulation (2) of regulation 29, shall take effect when a copy of it is served on the person to whom it applies or a notice of it is published in the *Gazette*, whichever is the earlier.

(5) Any person who contravenes any order made under subregulation (2) of section 29 shall be guilty of an offence.

Regulation 32. Exemption for pharmacy assistant and medical assistant.

Notwithstanding the provisions of regulations 3, 11(1) and 17, a pharmacy assistant or, in his absence, a medical assistant, employed in any hospital, clinic or institution wholly maintained by the Government at which human ailments are treated, may -

(a) possess, compound or mix; and

(b) upon a prescription prescribed by a registered medical practitioner or a registered dentist Division I, supply or dispense,

any psychotropic substance for the purposes of medical treatment of a patient:

Provided that such possession, supply, dispensing, compounding or mixing is made or conducted in accordance with the provisions of these Regulations relating thereto.

Regulation 33. Exemption for master of a ship.

(1) The master of any ship is deemed to be authorised to purchase and possess, and a licensed pharmacist is deemed to be authorised to sell or supply, such limited quantities of any psychotropic substances certified by a Port Health Officer of the port of call of the ship as may be necessary for the equipment of the ship for the purpose of first-aid or emergency cases.

(2) Every such sale or supply made under subregulation (1) shall be made in the manner prescribed under regulation 20, and that the certificate issued by the Port Health Officer shall be taken to mean a signed written order.

Regulation 34. Exemption of fees for government officers.

Any officer of the Government who imports, exports or requires a permit to purchase and use psychotropic substance in the course of carrying out his duty on account of the Government shall be exempted from any fees specified in these Regulations.

Regulation 35. Duty to give information, etc.

Any person who sells, supplies, manufactures, uses or otherwise has in his possession, any psychotropic substance shall -

(a) answer truthfully any questions and inquires put to him by a Licensing Officer, Drug Enforcement Officer, police officer not below the rank of Inspector or senior officer of Customs with respect to his obtaining, selling, supplying, manufacturing or using psychotropic substances; and

(b) in the case of a person who sells, supplies or manufactures psychotropic substance, disclose or produce to any such officer on demand the stock of psychotropic substance in his possession, and the register, book or other document relating to dealing in any such psychotropic substance.

Regulation 36. Offences for giving of false particulars, etc.

No person shall -

(a) furnish to any Licensing Officer, Drug Enforcement Officer, police officer or senior officer of Customs as true, information which he knows or has reason to believe to be false;

(b) enter in any register required to be kept under these Regulations any particulars which he knows to be false or does not believe to be true;

(c) make a false document for the purpose of obtaining any psychotropic substance;

(d) use as genuine any false document knowing it to be false for the purpose of obtaining the supply of psychotropic substance;

(e) for the purpose of obtaining any psychotropic substance, make a declaration or statement which was false in any particular.

FIRST SCHEDULE

FORM A

(Regulations 5(1), 6(1))

FORM A

**APPLICATION FOR AUTHORISATION TO IMPORT /
EXPORT* PSYCHOTROPIC SUBSTANCES**

The Licensing Officer,
Ministry of Health, Malaysia,
Kuala Lumpur,

I, (*name of applicant*)

a (*state profession*) practising

at (*business address*)

hereby apply for an authorisation to import / export * the psychotropic substance(s) specified hereunder.

2. The consignment of psychotropic substance(s) (hereinafter referred to as "the consignment") referred to in this application is to be imported from / exported to * with premises address at and will pass through the Malaysian Custom check point at

3. The consignment consists of -
(a) the following psychotropic substance(s) in pharmaceutical dosage form :

<i>Proprietary name</i>	<i>International non-proprietary name (INN) (if any)</i>	<i>Dosage form (tablet, ampoule, etc.)</i>	<i>Total units of dosage form</i>	<i>Account of psychotropic substance in each unit and total equivalent amount as base</i>

(b) the following psychotropic substance(s) in non-pharmaceutical dosage form:

<i>International non-proprietary name (INN), (lacking which the chemical name)</i>	<i>Form (solution, powder, etc.)</i>	<i>Total quantity of form</i>	<i>Total amount of psychotropic substance and equivalent amount as base</i>

4. Enclosed herewith is Money Order / Postal Order / Draft * No for the sum of Ringgit being fee for the import / export* authorisation.
 [Am. P.U.(A) 405/2018]

I, the undersigned, hereby declare that all the above-mentioned particulars are true and correct in any respect to the best of my knowledge and belief.

Date :

.....
Signature of applicant

* Delete where not applicable

FIRST SCHEDULE

FORM B

(Regulation

5(2)) FORM B

**CONVENTION OF PSYCHOTROPIC SUBSTANCES 1971
IMPORT AUTHORISATION**

Import Authorisation No :

In pursuance of regulation 5(2) of the Poisons (Psychotropic Substances) Regulations 1989, I, the Licensing Officer, hereby authorise *(here insert name and full postal address of importer)*

(hereinafter referred to as "the importer") to import from *(here insert name and full address of exporter)*

the following psychotropic substance(s) in the specified quantity :

.....
.....
.....
.....
.....

This authorisation is subject to the following conditions :

(a) the psychotropic substance(s) shall be imported through the Malaysian Customs check point at ; and

(b) at the time of importation, the psychotropic substance(s) and this authorisation shall be produced before the Drug Enforcement Officer or any proper officer of Customs, whose endorsement shall be obtained in the space provided in this authorisation.

This authorisation is valid from to

Date :

.....
Licensing Officer

ENDORSEMENT BY CUSTOMS / DRUG ENFORCEMENT OFFICER

I hereby certify that the psychotropic substances specified in this authorisation have been
duly imported on
(Specify amount if it varies from that specified in the authorisation)

Signature :

Official Stamp

Name :

(Enter particulars below if importation is conducted by agent of importer)

Name of agent :

NRIC No. :

Signature of agent :

FIRST SCHEDULE

FORM C

(Regulation 6(2))

FORM C

**CONVENTION ON PSYCHOTROPIC SUBSTANCES 1971
EXPORT AUTHORISATION**

Export Authorisation No :

In pursuance of regulation 6(2) of the Poison (Psychotropic Substances) Regulations 1989, I, the Licensing Officer, hereby authorise *(here insert name and full postal address of exporter)*

(hereinafter referred to as "the exporter") to export to *(here insert name and address of importer)*

the following psychotropic substance(s) in the specified quantity :

.....
.....
.....
.....
.....

This authorisation is subject to the following conditions :

(a) the psychotropic substance(s) shall be exported through the Malaysian Customs check point at; and

(b) at the time of exportation, the psychotropic substance(s) and this authorisation shall be produced before the Drug Enforcement Officer or any proper officer of Customs, whose endorsement shall be obtained in the space provided in this authorisation.

This authorisation is valid from to

Date :

.....
Licensing Officer

ENDORSEMENT BY MALAYSIAN CUSTOMS / DRUG ENFORCEMENT OFFICER	ENDORSEMENT BY GOVERNMENT OF IMPORTING COUNTRY
I hereby certify that the psychotropic substances specified in this authorisation have been duly exported on	I hereby certify that the psychotropic substances specified in this authorisation have been duly imported. (Specify amount imported if it varies from that stated in the authorisation).
Signature :	Signature :
Name :	Designation :
	Date :
Official Stamp	Official Stamp
	(Please return copy to : The Licensing Officer, Ministry of Health, Malaysia)

SECOND SCHEDULE

(Regulation 9)

LIST OF PSYCHOTROPIC SUBSTANCES TO BE ACCOMPANIED WITH EXPORT AUTHORISATION ON IMPORT OR WHILE IN TRANSIT

1. Amfetamine ((?)-2-amino-1-phenylpropane)

Dexamfetamine ((+)-2-amino-1-phenylpropane)

Fenetylline (*dl*-3, 7-dihydro-1, 3-dimethyl-7-(2-[(1-methyl-2-phenylethyl) amino] ethyl)-1H-purine-2, 6-dione)

Levamfetamine (*l*-methylphenethylamine)

Levomethamphetamine (*l*-N, -dimethylphenethylamine 3-(*o*-chlorophenyl)-2-methyl-4 (3H)-quinazolinone)

Mecloqualone (3-(*o*-chlorophenyl)-2-methyl-4 (3H)-quinazolinone)

Methamfetamine ((+)-2-Methylamino-1-phenylpropane)

Methamphetamine racemate ((?)-N, -dimethylphenethylamine)

Methaqualone (2-methyl-3-*o*-tolyl-4 (3H)-quinazolinone)

Methylphenidate (2-phenyl-2-(2-piperidyl) acetic acid, methylester)

Phencyclidine (1-(1-phenylcyclohexyl) piperidine)

Phenmetrazine (3-methyl-2-phenylmorpholine)

Secobarbital (5-allyl-5-(1-methylbutyl) barbituric acid)

2. The salts of the substances specified in paragraph 1 of this Schedule wherever the existence of such salt is possible.

3. Any preparation, solution, compound, mixture or product containing one or more of the substances specified in paragraphs 1 and 2 of this Schedule.

THIRD SCHEDULE

FORM D

(Regulation 15(1))

FORM D

**APPLICATION FOR A PERMIT TO PURCHASE AND USE
PSYCHOTROPIC SUBSTANCES**

To : The Licensing Officer

Through :
.....
.....
.....

I,, being engaged in the business of
..... whose business address is
..... hereby apply for a permit to purchase and use the following
psychotropic substance(s) :

*International Non-
Proprietary Name
(INN) and form*

Strength

Quantity

Office Use

for the purpose of

2. Enclosed herewith is Money Order / Postal Order / Draft * No
..... for the sum of Ringgit being
fee for the above-mentioned permit.

Date :

.....
Signature of applicant

THIRD SCHEDULE

FORM E

(Regulation 15(2))

FORM E

PERMIT TO PURCHASE AND USE PSYCHOTROPIC SUBSTANCE

Permit No.

In pursuance of regulation 15(1) of the Poisons (Psychotropic Substances) Regulations 1989, I, the Licensing Officer, hereby Grant this permit to to purchase the following psychotropic substance(s) not exceeding the amount specified:

to be used only for the purpose of and subject to the conditions overleaf.

This permit is valid from to

Date :

.....
Licensing Officer

CONDITIONS OF PERMIT

1. The permit holder shall maintain a bound record book or a separate part of such record book for each of the psychotropic substance specified in this permit, and shall enter therein the name and form of the psychotropic substance, name and address of supplier, date and amount received, date and amount used and stock in balance.
2. The permit holder shall inform the Licensing Officer by registered post of each purchase of psychotropic substance made, not later than fourteen days after the receipt of the psychotropic substance stating the name and form of psychotropic substance received, amount and date received, and the name and address of supplier.

FOURTH SCHEDULE

(Regulation 31)

1. The advisory committee shall consist of -

(a) in the case of a registered pharmacist, the Director General of Health, the Director of Pharmaceutical Services, and two registered pharmacists not in the public service appointed by the Minister;

(b) in the case of a registered medical practitioner, the Director General of Health, The Director of Medical Services, and two registered medical practitioners not in the public service appointed by the Minister;

(c) in the case of a registered dentist Division I, the Director General of Health, the Director of Dental Services, and two registered dentists Division I not in the public service appointed by the Minister; and

(d) in the case of a veterinary surgeon, the Director General of Health, the Director of Veterinary Services, and two veterinary surgeons not in the public service appointed by the Minister.

2. (1) The person against whom the order is to be made shall be entitled to appear before and be heard by the advisory committee in person.

(2) An advisory committee may regulate its own procedure.