

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF
THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

BRAZIL

Communicated by the Government of Brazil

NOTE BY THE SECRETARY GENERAL – In accordance with the relevant Articles of the International Treaties on Narcotic Drugs and Psychotropic Substances, the Secretary-General has the honour to communicate the following legislative text.

E/NL.1977/53

Ministry of Health National Control Division National Medical and Pharmaceutical Control Service

ORDER NO. 26 OF 26 JULY 1974

The Official in Charge of the National Medical and Pharmaceutical Control Service, in exercise of the powers vested in him under article 36 (XX) of the regulations approved in Order No. 304 of 15 October 1970, hereby issues the following instructions on the production, marketing prescription and use of drugs and proprietary pharmaceutical preparations which are capable of causing changes in the higher nervous functions or which require effective and continuous medical supervision owing to the possibility of their inducing undesirable side—effects.

1. PRESCRIPTION

- 1.1. The direct sale to the public of the drugs or proprietary pharmaceutical preparations listed in schedules I and II hereto shall be confined to pharmacies and chemist's shops which are specially licensed for that purpose; it may not take place except on presentation and retention of a prescription made out by a duly qualified practitioner.
- 1.2. Prescriptions which include the drugs or proprietary pharmaceutical preparations mentioned in paragraph 1.1 may not be dispensed unless:
 - (a) They are made out by a duly qualified physician, dental surgeon or veterinarian;
- (b) They are written on a prescription form taken from the practitioner's counterfoil book and giving his name, his registration number in his professional association and the address of his consulting rooms and/or residence;
- (c) They give the full name and address of the patient and directions for use of the medicine prescribed, and bear the date and the autograph signature of the practitioner;
- (d) They are written out legibly in full in Portuguese in ink and in the practitioner's own handwriting;
 - (e) The amounts prescribed are given in Arabic numerals and in full;
 - (f) The amounts prescribed are also given in the legal units of measurement in force in Brazil;
- (g) In the case of an animal, the prescription states the species, weight and other characteristics, the place where the animal is kept and the name and address of its owner, in addition to the particulars specified under (a), (b), (c) "in fine", (d), (e) and (f) above.
- 1.5. In cases of emergency and in the absence of the counterfoil book referred to in subparagraph (b) of the foregoing paragraph, the prescription may be written on other paper, provided that the practitioner gives all the relevant details and indicates why the prescription requires urgent attention.

- 1.4. In public, private or charitable medical or veterinary hospital or parahospital establishments, the medicines listed in the schedules hereto may not be supplied to day patients or out-patients except on a prescription which is written on the headed paper of the establishment by a practitioner who is on the staff of the establishment or can show that he is attending the patient concerned, and which complies in addition with the requirements in paragraph 1.2 of the present Order.
- 1.5. Only one formulation of any proprietary pharmaceutical preparation listed in the schedules hereto shall appear on each prescription.
- 1.6. The practitioner signing the prescription shall take full responsibility for the quantity prescribed in it.
- 1.7. The prescriptions referred to in the present Order shall be valid for 30 (thirty) days from the date on which they are issued.
- 1.8. Prescriptions by dental surgeons for the proprietary pharmaceutical preparations covered by the present Order shall comply with the provisions of sections I and II of article 6 of Act No. 5,081 of 24 August 1966.
- 1.9. The maximum prescribable amount of any drug referred to in the present Order shall be the recognized dose to be taken in 72 (seventy-two) hours.
- 1.9.1. Prescriptions for larger quantities shall bear the prior authorization of the competent supervisory authority.
- 1.10. Public or private research and/or teaching establishments may make use for those purposes of drugs and proprietary pharmaceutical preparations covered by the present Order provided that the National Medical and Pharmaceutical Control Service has specifically authorized the entire research programme in question.
- 1.10.1. The drugs and products referred to in the preceding paragraph may not be handled except by such research workers, and on such research premises, as are specified in the programme.
- 1.10.2. The National Medical and Pharmaceutical Control Service shall forward the appropriate competent organ a copy of the approved research programme for information and examination as required.

2. RECORDS

- 2.1. Industrial pharmaceutical enterprises handling the drugs referred to in the present Order shall record in the appropriate book or other form of record, authenticated by the competent supervisory health authority, all their operations relating to the drugs in question, including the storage of the finished product.
- 2.2. Pharmacists, chemist's shops, drug wholesalers, representatives and distributors of industrial pharmaceutical enterprises and importers and exporters shall record in the appropriate book or other form of record, authenticated by the competent supervisory health authority, all acquisitions, transactions and sales of the drugs and proprietary pharmaceutical preparations listed in the schedules hereto.
- 2.3. Prescriptions dispensed for proprietary pharmaceutical preparations covered by the present Order need not be entered in the prescription book where they have already been recorded in the appropriate book or other form of record with sufficient details to identify them in full.
- 2.4. Where there is an entry in the prescription book, it shall suffice to refer in the appropriate book or other form of record to the number of the entry and the total quantity of units supplied.
- 2.5. Prescriptions shall be kept on file in chronological order in the establishments concerned for inspection and approval by the competent health authority for 1 (one) year, after which they may be destroyed.
- 2.6. Hospital establishments (hospitals, mursing homes, clinics and similar institutions) shall record in the appropriate book or other form of record all acquisitions, transactions and uses made of drugs and products to which the present Order refers.
- 2.6.1. Where the hospital unit does not possess its own dispensary, responsibility for these records shall rest with the director of the establishment as authorized by the local health supervisory body.
- 2.7. The person in charge of the over—all research programme referred to in paragraph 1.10 shall also be responsible for the control, supervision and recording of the drugs and products authorized for the research in question, in conformity with the instructions and other regulations on the subject at present in force or to be issued in the future; he shall also be required to provide any information requested by the competent health supervisory authority.

- 2.8. In commercial transactions between industrial firms, traders, hospital and parahospital establishments, teaching establishments and medical assistance organizations, fiscal vouchers shall on issue show clearly and as separate items the names of the drugs or proprietary pharmaceutical preparations subject to the provisions of the present Order, and a copy of each such voucher shall be filed and be available to the health supervisory authorities for a period of 1 (one) year.
- 2.8.1. Enterprises using mechanized accounting systems shall be at liberty to prepare a daily list of the numbers of the fiscal vouchers relating to the pharmaceutical products subject to the requirements of the present Order, as a substitute for the vouchers themselves.

3. LABELLING AND PACKAGING

- 3.1. The proprietary pharmaceutical preparations listed in schedule II hereto shall be labelled and packaged as follows:
- (a) Injectable preparations shall have their name and the composition of the basic component printed on the bottle and be put up in boxes containing 5 (five), 10 (ten) or 15 (fifteen) ampoules or a phial with the corresponding dose when intended for sale to the public, and 25 (twenty-five), 50 (fifty) or 100 (one hundred) when intended for use by hospital and parahospital organizations;
- (b) Proprietary pharmaceutical preparations in solid form shall be put up in distinctive packaging for sale to the public in amounts of 20 (twenty) dosage units in the case of tablets, dragées, capsules and pills and in amounts of 5 (five) units in the case of suppositories; when intended for use by hospital and parahospital organizations, they shall be put up in quantities of 50 (fifty), 100 (one hundred) and 200 (two hundred) dosage units;
- (c) Proprietary pharmaceutical preparations to be taken orally in the form of powder or granulates shall be put up in distinctive packaging in amounts corresponding in active substance to 10 (ten)or 20 (twenty) tablets when intended for sale to the public, and to 100 (one hundred) tablets when intended for use by hospital and parahospital organizations.
- (d) Proprietary pharmaceutical preparations in liquid form to be taken orally shall be put up in quantities of 100 (one hundred) and 200 (two hundred) millilitres and of 20 (twenty) millilitres in the case of dropper containers;
- (e) The National Medical and Pharmaceutical Control Service shall be responsible for deciding the quantity which each package of a topical remedy shall contain.
- 3.2. Proprietary pharmaceutical preparations covered by the present Order and authorized specifically for use as anti-spasmodics may be put up in packages of 100 (one hundred) dosage units for sale to the public and 500 (five hundred) units for hospitals.
- 3.3. The labels and wrappers of the products listed in the schedules hereto, shall, in addition to meeting the licensing requirements already prescribed, bear the following wording:

"TO BE SOLD ON A MEDICAL PRESCRIPTION WHICH MUST BE SURRENDERED"

- 3.3.1. Industrial pharmaceutical enterprises shall be allowed 180 (one hundred and eighty) days in which to comply with the provisions of paragraphs 3.1, 3.2 and 3.3.
- 3.4. In the case of preparations whose labels already bear the wording previously required to the effect that the prescription must be surrendered, failure to comply with paragraph 3.3.1 of the present Order shall not constitute an infringement of that paragraph.
- 3.5. Manufacturers of proprietary pharmaceutical preparations which now fall for the first time in the category of preparations subject to surrender of prescription on sale shall notify the National Medical and Pharmaceutical Control Service and the corresponding State, territorial, or federal district organ, according to their location, of the number of the last batch of products placed on sale which do not comply with paragraphs 3.1, 3.2 and 3.3.

4. SAMPLES

- 4.1. Samples of the proprietary pharmaceutical preparations covered by the present Order may not be distributed except under the supervision of the competent federal, State and territorial health authorities and in the following circumstances:
- (a) Where specifically ordered by a physician, dental surgeon or veterinarian on a prescription form taken from the practitioner's counterfoil book and bearing the date and his autograph signature, up to a maximum of four regulation packages of samples per order;
- (b) For clinical purposes, in hospital and parahospital establishments, on the responsibility of a qualified practitioner and as part of a specific programme authorized by the director of the establishment with the prior approval of the National Medical and Pharmaceutical Control Service.

4.2. Labels and wrappers of samples shall clearly bear the following wording:

"PRODUCT SUBJECT TO RESTRICTED SALE AND USE"

- 4.3. Industrial pharmaceutical enterprises and other establishments which distribute samples of the proprietary pharmaceutical preparations covered by the present Order shall record such operations in the appropriate book or other form of record.
- 4.3.1. Vouchers evidencing distribution of samples shall be retained by the distributing establishment for a period of 1 (one) year for verification and approval by the competent health authority.
- 4.3.2. The fiscal consignment voucher shall serve as a return voucher of proof if duly signed by the medical practitioner, dental surgeon or veterinarian.
- 4.4. Industrial pharmaceutical enterprises shall be allowed 90 (ninety) days in which to comply with the provisions relating to the distribution of samples.

5. GENERAL PROVISIONS

- 5.1. The National Medical and Pharmaceutical Control Service and the corresponding State, territorial or federal district health authority shall be notified whenever the manufacture and sale of products subject to the present Order begins or ends; the notification shall include the number of the last batch manufactured and take place within 30 (thirty) days after the cessation of manufacture or sale.
- 5.2. Failure to comply with the present Order shall be a health offence under Decree Law No. 785 of 25 August 1969 and be subject to the penalties therein provided.
- 5.2.1. Persons who in any way assist in committing the above offence or who profit from it shall be jointly and severally liable for the offence.
- 5.3. In the event of the bankruptcy or judicial liquidation of any establishment manufacturing or selling drugs or proprietary pharmaceutical preparations covered by the present Order, the judicial authority shall give notice to the competent health authority to receive on deposit any stocks taken into safe keeping or forming part of the liquidation assets.
- 5.4. Any sale by judicial auction of the substances or proprietary pharmaceutical preparations listed in the schedules hereto shall take place in the presence of representatives of the National Medical and Pharmaceutical Control Service or related health organs empowered by the Service, and bidding shall be confined to enterprises or establishments lawfully authorized by the competent health authority.
- 5.5. The provisions of the present Order shall also apply to products without a trade name which are licensed or authorized by the National Medical and Pharmaceutical Control Service.
- 5.6. Advertisements for the drugs listed in schedule I hereto and for proprietary preparations containing them may not appear except in technical and scientific journals or publications strictly intended for physicians, veterinarians and, as the case may be, dental surgeons.
- 5.7. Industrial pharmaceutical enterprises holding licences for proprietary pharmaceutical preparations which are not mentioned in schedule II but contain drugs listed in schedule I hereto shall within 30 (thirty) days inform the National Medical and Pharmaceutical Control Service of the name of the preparation concerned, the corresponding process number and the number and date of the licence, whether or not the product has been manufactured and placed on sale.
- 5.8. For the purposes of the present Order, "appropriate book" is a book conforming to specimen No. 2 of the General Instructions on the Use and Marketing of Narcotic Drugs and "other form of record" is any separate copy of the wording of a sheet of that book.
- 5.9. The drugs and proprietary pharmaceutical preparations listed in schedules I and II hereto shall be kept under the strict control of the pharmacist or person in charge of the establishment concerned.
- 5.10. Schedules I and II hereto are hereby approved.
- 5.11. Orders No. 5/69 (text and schedule I), 21/69, 28/69 (text), 30/69, 31/69, 32/69, 38/69, 3-70, 3-71, 18-71, 19-71 and 24-71 are hereby repealed.
- 5.12. The provisions of the present Order shall apply to the proprietary pharmaceutical preparations listed in schedule II to Order No. 5/69 and in the instruments supplementing that Order and to other similar preparations whose licences require them to be sold on surrender of a medical prescription.
- 5.13. The present Order shall come into force on the date of its publication.

Dagoberto M. de M. Chaves Official in Charge, National Medical and Pharmaceutical Control Service

SCHEDULE I TO ORDER NO. 26-74

Substances

Acepromazine 1/ Fenproporex Oxypertine Amfepramone (diethylpropion) Flupentixol Papaverine diethylbarbiturate Amitriptyline Fluphenazine Penfluridol Azacyclonol Flurazepam Perphenazine Benactyzine Glutethimide Periciazine (propericiazine) Benzoctamine Haloperidol Phacetoperane (levophacetoperane) Benzquinamide Halothane Phenaglycodol Beta-piperonyl-isopropyl-hydrazine <u>Homofenazine</u> Phenelzine Biperiden Hydrochlorbenzethylamine Pheniprazine Broma zepam Hydroxydione sodium Phenprobamate Butaperazine Imiclopazine Phenylpropanolamine Butriptyline Imipramine Phthalimidoglutarimide (thalidomide) Captodiame Imipramine N-oxide Pimozide (R 6238) Chloral betaine Iproclozide Pipamperone Chloral hydrate <u>Isocarbo</u>xazid Pipradrol Chlordiazepoxide Isopropyl-crotonyl-urea Prazepam Chlorhexadol Ketamine Proclorperazine Chlorimipramine Levomepromazine Promazine Chlorpromazine Lorazepan Propanidid Chlorprothixene Maprotiline Propiomazine Clonazepam Mecloqualone Prothipendyl Clothiapine Medazepam Protriptyline Cyclarbamate Mefenorex Quinidine phenylbarbiturate Cyclexedrine Mepazine Sulpiride Deanol aceglumate Mephenoxalone Deanol acetamidobenzoate (DMAE) Temazepam Meprobamate Tetrachloroethylene N-demethyldiazepam Mesoridazine Thioproperazine <u>Desipramine</u> Methaqualone Thioridazine Dextropropoxyphene <u>Methocarbamol</u> Thiotixene Diazepam Methopromazine Tranylcypromine Dibenzepin Methoxyflurane Diethylamine phenylbarbiturate Trazodone <u>Methylpentynol</u> Trichloroethylene Dimetracrine Methyprylon Triclofos Dixyrazine Methysergide Trifluoperazine <u>Doxepin</u> Moperone Trifluperidol Droperidol Nialamide Triflupromazine Ectylurea Nitrazepam Trihexyphenidyl Emylcamate Nomifensine Ethclorvynol **Trimipramine** <u>Nortriptyline</u> Ethinamate Noxiptyline

Opipramol

Oxazepam

Oxyfenamate

Ethyl chloride

Fencamfamin

<u>Fenfluramine</u>

^{1/} Note by the Secretariat: International non-proprietary names are underlined.

SCHEDULE II TO ORDER NO. 26-74

form or manufacturer

form or manufacturer

Chlorpromazine - any pharmaceutical

Abistil Bloq Abulemin Butial Abulemin AP Byrofen Abulempax AP Calmarian Adipenan Calmin Adrepress Calmine Adumbran Calmix Aflitil Calmociteno Agedal Calmogen Akineton Calmovita Akneton Retard Calude Alertin Carbam Aletan Catron <u>Chlordiazepoxide</u> - any pharmaceutical

Algafan (injectable solution)

Alival

Azepin

Amfepramone - any pharmaceutical form

or manufacturer

(diethylpropion)

Amplictil Clorium Amprazin Clorprazin

Anafranil Clorprasin - simple

Clonix

Anatensol Conco rdin Anatensol Depot Corpobel Anatensol P Corporex Anatrium Cosmorax Angustil Cosmosedin Anobesina Covatin Anograx Cuiat-D Anosedil Cuait-N Ansiax Daforin

Ansiepax Dalmodorm Ansiex Dardanin Ansiolax Deastil Ansiolin Dedalen Ansiolon Delgar Ansiopan Deprex Ansiotex Depromal Apex Deseril Artane Desobesi Astress Desobesi M

any pharmaceutical Belupan Dextropropoxyphene -

Despertil

form or Bendialix manufacturer

Bensofepin Dialor Beta-Clor Diamicil Biostil Dianorex Biotrol Diapason Diatrex Evadyne Diatrex AP Eventin Diazelin Farmoglan Diazelong Fastinan Diazepam - any pharmaceutical form Fastinan AP or manufacturer Fatinil

Diazetard Fatinil AP Dienpax

Fencamfamine - any pharmaceutical form Dienpax AP

or manufacturer

Diepin Fenidex Diestren Fenidex AP Dietex Fenorex Diethylpropion tablets ("Paulifarma") Fenorex AP

Dimagrin Fenproporex - any pharmaceutical form

or manufacturer

Dinamagra AP Fenproxin Dipiperon Fidepax Ditisan Flobesin Dobesix LP Fluothane Dogmalid Flupsixol Dogmatil Flurazepol Doloxene (injectable solution) Fomenon Doloxone H (injectable solution)

Fortzepam Dominal Frenafom Dorevane Frenquel Doriden Frumidan Dormex Gamafenil Doxepin - any pharmaceutical form or manufacturer Gamaquil

Drimuel Gardenal

Droperidol Gardenal for children

Enlonyl Gardenalinas Elegatin Gentaplexin Elepsin Gulastop Elmonal Haloperidol Elmonal gel Halothane

Emagrecil Halothane - Ayerst liquid anaesthetic

Emagril Hartol Emagrin Hastil Emotil Helmitan Empax Hibinil Epilpax Hidropan Equilid Hipnax Equilipan Hipofagin Ergotonil Horminal Esbeltina Hypnolon Esbeltrat Ifag

Esucos Imipramine - any pharmaceutical form

or manufacturer

Imipraz Euforil

Etumine Wander

Indenil Lipostil AP Indunox Lipovita Inibex Lipovita AP Inobesin Lipozid Inobesin AP Liprorex Insidon Lisalipol Insonium Lisemex Isodepril Lisozepan Izoazina Listica Jesal Lorax Kalmoxil Lorazam

Kazepan Lorazepam - any pharmaceutical form or manufacturer

Kelene

Lorenpax Ketalar Loril Kiatrium Lotawin Kondoxan Ludiomil Lepenil Luminal Levanxol Luminaletas Levil

Lunipax Levil for children Luzepin

Lexotan

Medalen Lexotan - suspension for children Madar Librioum Magrene Lidanar Magress Lidepran Majeptil Limbritol Mandrix Linopen Marplon Linopen AP Maxipaz Lipenan AP

Maxizepan Lipese Medaciteno Lipex Medalium Lipidin Medazen Lipoclase

Medazepam - any phrmaceutical form or Lipoclasse

manufacturer

Lipoclasse AP Medazepol Lipoex Medazepol AP Lipogen

MedazonLipograssil Melleril Lipolin

Melleril for children Lipolin AP Melleril - 200 Retard Lipolisine

Melpazil Lipolisine AP Meprobal Lipomax

Meprobamate - any pharmaceutical form or Lipomax AP manufacturer

Lipoplex Meprofenil Liporex Meprolen Liporexin Mepromax Lipostil Meproneuran Meproneuran with phenobarbital

Neozine for children Nervium

Meprosan Meprosay

Neuleptil

Meprosedan

Neuleptil for children

Meprosin for children

Neurap Neurazon Neuriplex

Mequalon Messapia

Neuritex Neurium

Metagen Metarelax Metolil

Neurocontrol Neurominal

Metdil A Metolil S Neuroplegine
Neurozulin

Metolil T

Niamid

Mezepan

Niamid Parenteral in powder form

Miltown Minifage Nilipoid AP

Ministan

Nirvalene

Miolaxene

Nitrazepam - any pharmaceutical form

or manufacturer

Modelin Miorel Miorrelax Nitrazepol Nitrenpax Niveltress

Moderafom

Niveltress Retard

Moderakid Moderamin Moderan AP Noan AP Noadsied Nobese

Moderasin

Moderat

Moderex

Moderil

Nobrium Noctazepam Noludar Norexil Norexon

Moderine Modecyr

Norexon Retard

Modulan Mogadon Notaral Novapirid Novazepam

Motival dragées ("Filmlok")

Noveril Wander

Motivina Muconil Mutabon Mutabon A Mutabon D

Nubarene Oasil-Simes Obelex

Nardil Natisedine Navane Negatan Negatan AP Neostress

Neozine

Obelex
Obenil
Obesitol
Obesonon
Obex
Oblivon
Odocilin
Onirium
Orap

Oxabril Psicopax Oxatrat Psicoplex Oxazelin Psicossedin Oxazepam - any pharmaceutical form Psicossedin - 5 mg - for infants or manufacturer Psiquium Oxazepol Quantril Pacatal Quetil Pacienx Quipax Pacintran (long-lasting effect) Randolectil Pacintran N (long-lasting effect) Raupentin Pacintran DN (long-lasting effect) Redulip Pansedans Redux Pantogenina Redufome Parnate Regin Paseden Regi-men Paxate Relaxan Paxton Relaxil Pentrane Relax-Pam Perphenazine - any pharmaceutical form Repesan or manufacturer Reprimil Pertofran Reverax Pesex Revonal Pesex AP Rivotril Pesonex Robaxin Phenobarbital - any pharmaceutical form or manufacturer Samida de Angeli Phthalimidoglutarimide - any pharmaceutical Saninger form or manufacturer Sedacalm (thalidomide) Sedavier Placimin Sedax Plaxana Sedolin Plegicil Sedomepril Ponderex Sedotex Ponderex AP Sещар Ponderil Serenex Pondinol "Roche" Serenium Ponil Sevinol Ponsital Sevinol Reptabs Prolinan Sicomatil Promazionon Siledin Promilene Sinequan Propiofen Sintomax Proporex Sintonan Proporex AP Siplarol Proteuforil Siquil Prozepin Sofrosine Psicobione Sonebon Psicodin Sonex Psicofar Sonin

Psicolatil

Sonipam Sonium Sonoasil Sonobel Sonopax Sonotal Sonotrat Stabilin Stelapar No. 1 Stelapar No. 2 Stelazine Stenorol Striatan C Sulpiride - any pharmaceutical form or manufacturer Sulpiril Sultranquin Suprefon Surmontil Tacital Takan Tementil Temiran Temiran Dospan Tempase Tensil Tensobel Tensocron Tensolisin Tenzepam Tetrachloroethylene - any pharmaceutical form or manufacturer Tofranil Tombran Trancalmat Tranil Tranquiex Tranquil Tranquilase Tranquilid Tranquilin Tranquimax Tranquisan Tranquix Tranxilene Tricioryl Trifluoperazine - any pharmaceutical form

or manufacturer

or manufacturer

Triflupromazine - any pharmaceutical form

Trihexyphenidyl - any pharmaceutical form or manufacturer Trilafon Trilafon Reptabs Trilene Triperidol Tryptanol Ultrazepam Usempax Usempax - long-lasting effect Vagonal Valium Vate Vermucina Viadril Vividyl Vividyl (nortriptylene hydrochloride, Lilly) Zepanil Zepased