UNITED NATIONS

E/NL.1978/7-10
18 June 1979
ENGLISH ONLY

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 texts.

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Library of the Court of Criminal Justice of Sao Paulo Federal Legislation

ACT NO. 6,368 of 21 OCTOBER 1976

Enacting measures for the prevention and suppression of illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence, and other provisions.

I, the President of the Republic,

Declare that the National Congress has passed, and that I approve, the following Act:

CHAPTER I

Prevention

Article 1. Every natural and juridical person shall assist in preventing and suppressing illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence.

Sole paragraph. A juridical person failing to co-operate, when requested to do so, in government plans for preventing and suppressing illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence shall forfeit, by decision of the competent organ or authority, any grant or subsidy which it may be receiving from the Union, States, Federal District, Territories or municipalities or from their autonomous bodies, public enterprises, mixed companies or foundations.

Article 2. The planting, cultivation, harvesting and use by private individuals of any plant from which it is possible to extract a narcotic drug or substance which causes physical or psychic dependence shall be prohibited throughout the territory of Brazil.

Para. 1. Wild or cultivated plants of this kind in existence in Brazilian territory shall be destroyed by the police authorities, except in the cases specified in the following paragraph.

Para. 2. The cultivation of such plants for therapeutic or scientific purposes shall not be permitted except with the prior authorization of the competent authorities.

Para. 3. A licence from the competent health authority, and compliance with the other requirements of the law, shall be required for the extraction, production, manufacture, processing, preparation, possession, import, export, re-export, dispatch, transport, display, offer, sale, purchase, exchange, transfer or acquisition for any purpose of a narcotic drug or substance which causes physical or psychic dependence or of a raw material which can be used to prepare such a drug or substance.

Para. 4. The acquisition of medicines on medical prescription in accordance with any law or regulation shall be excepted from the requirement set out in the previous paragraph.

Article 3. Activities relating to the prevention, detection and suppression of traffic in and use of narcotic drugs or substances which cause physical or psychic dependence shall constitute an integrated national prevention, control and suppression system composed of all the organs which perform these functions at the federal, state and municipal levels.

Sole paragraph. The system to which this article refers shall be instituted by an executive decree which shall provide for over-all co-ordination and control machinery in respect of the activities concerned and for co-ordination and control machinery specifically within the spheres of competence of the Federal Government, the State Governments and the municipal authorities.

Article 4. Persons in charge of educational or hospital establishments and of social, cultural, recreational, sports and benevolent organizations shall, by common consent and under the technical guidance of specialized authorities, adopt all necessary measures to prevent illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence near or within the premises in which their activities take place.

Sole paragraph. The aforementioned persons shall be legally and administratively liable for non-observance of the provisions of this article.

Article 5. Teachers' training courses shall include instruction on narcotic drugs and substances which cause physical or psychic dependence, so that information on these drugs and substances may be transmitted with due respect for the scientific principles involved.

Sole paragraph. The curricula for natural science subjects forming part of first-grade study courses shall include compulsory periods devoted to explanations about the nature and effects of narcotic drugs and substances which cause physical and psychic dependence.

Article 6. It shall be within the sole competence of the Ministry of Health, through its specialized organs, to issue general or specific instructions relating to the prohibition, restriction, supervision and control of the production, marketing and use of narcotic drugs or substances which cause physical or psychic dependence and of proprietary pharmaceutical preparations containing such drugs.

Sole paragraph. The powers established under this article may, with regard to supervision and control, be delegated to similar organs in the States, Federal District and Territories.

Article 7. The Union may conclude agreements with the States for the prevention and suppression of illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence.

CHAPTER II

Treatment and rehabilitation

Article 8. Persons dependent on narcotic drugs or on substances which cause physical or psychic dependence shall be subject to the measures prescribed in this chapter.

Article 9. The health services of the States, Territories and Federal District shall, wherever necessary and possible, have establishments of their own for treating persons dependent on the drugs and substances mentioned in the present Act.

Para. 1. Pending the creation of the establishments referred to in this article, existing units of health services shall be adapted for the purpose.

Para. 2. The Ministry of Social Welfare shall take steps to ensure that the provisions of this article, including paragraph 1 thereof, are also observed in its health services.

Article 10. Patients shall be detained in hospital for treatment when the clinical diagnosis of the dependent of the nature of his psycho-pathological symptoms so requires.

Para. 1. When detention in hospital is found unnecessary, the dependent shall undergo treatment as an out-patient under the supervision of the appropriate social welfare service.

Para. 2. Public and private hospital establishments and clinics which receive dependents for treatment shall send to the competent department by the tenth day of each month a statistical analysis of the cases dealt with during the previous month, stating the code number of the illness under the classification approved by the World Health Organization, but they need not mention patients' names.

Article 11. A dependent who has committed a punishable offence and been sentenced to a term of imprisonment or custodial security measure shall undergo treatment in the clinic attached to the penal establishment where he is serving his sentence.

CHAPTER III

Offences and penalties

Article 12. The import or export, dispatch, preparation, production, manufacture, acquisition, sale, display for sale or offer, supply, gratuitous or otherwise, storage, transport, carrying upon the person, keeping, prescription, administration or delivery in any form whatsoever for consumption, of a narcotic drug or substance which causes physical or psychic dependence, without authorization or in breach of any law or regulation:

Penalty: rigorous imprisonment for 3 (three) to 15 (fifteen) years and payment of 50 (fifty) to 360 (three hundred and sixty) times the day/fine.

Para. 1. A person shall be liable to the same penalties if he unlawfully:

I. Imports or exports, dispatches, produces, manufactures, acquires, sells or displays for sale or offers, supplies, gratuitously or otherwise, stores, transports, carries on his person or keeps any raw material intended for the preparation of a narcotic drug or of any substance which causes physical or psychic dependence;

II. Sows, cultivates or harvests plants intended for the preparation of a narcotic drug or of any substance which causes physical or psychic dependence.

Para. 2. A person shall also be liable to the same penalties if he:

I. Induces, incites or assists any person to use a narcotic drug or substance which causes physical or psychic dependence;

II. Uses a place or premises which he owns, occupies, manages, guards or keeps watch over or consents to its use by another person, gratuitously or otherwise, for the abuse of or illicit traffic in a narcotic drug or substance which causes physical or psychic dependence.

III. Contributes in any way to encouraging or spreading the abuse of or illicit traffic in narcotic drugs or substances which cause physical or psychic dependence.

Article 13. The manufacture, acquisition, sale, supply, gratuitous or otherwise, possession or keeping of machinery, apparatus, an instrument or any object intended for the manufacture, preparation, production or processing of a narcotic drug or of any substance which causes physical or psychic dependence, without authorization or in breach of any law or regulation:

Penalty: rigorous imprisonment for 3 (three) to 10 (ten) years and payment of 50 (fifty) to 360 (three hundred and sixty) times the day/fine.

Article 14. The joining together by 2 (two) or more persons for the purpose of committing, repeatedly or otherwise, any of the offences mentioned in articles 12 and 13 of the present Act:

Penalty: rigorous imprisonment for 3 (three) to 10 (ten) years and payment of 50 (fifty) to 360 (three hundred and sixty) times the day/fine.

Article 15. The culpable prescription or administration by a physician, dentist, pharmacist or nursing practitioneer of a narcotic drug or of any substance which causes physical or psychic dependence, either in doses obviously greater than is necessary or in breach of any law or regulation:

Penalty: ordinary imprisonment for 6 (six) months to 2 (two) years and payment of 30 (thirty) to 100 (one hundred) times the day/fine.

Article 16. The acquisition, keeping or carrying upon the person for one's own use of a narcotic drug or of any substance which causes physical or psychic dependence, without authorization or in breach of any law or regulation:

Penalty: ordinary imprisonment for 6 (six) months to 2 (two) years and payment of 20 (twenty) to 50 (fifty) times the day/fine.

Article 17. Breaking in any manner the seals referred to in article 26 of the present Act:

Penalty: ordinary imprisonment for 2 (two) months to 6 (six) months or payment of 20 (twenty) to 50 (fifty) times the day/fine, without prejudice to any administrative penalties to which the offender may be liable.

Article 18. The penalties for the offences defined in the present Act shall be increased by 1/3 (one-third) to 2/3 (two-thirds):

I. In cases of trafficking with a foreign country or extraterritoriality of the criminal law;

II. When the offender, in committing the offence, has taken advantage of a public office connected with the suppression of crime or when, although not a holder of a public office, he discharges custodial or supervisory duties;

III. If any offence arises in association with or is directed against persons under the age of 21 (twenty one) years or a person whose capacity for discernment or self-control is for any reason diminished or extinguished;

IV. If any of the acts of preparation, commission or consumption take place near or within an educational or hospital establishment, the premises of a student body or of any social, cultural, recreational, sports or benevolent organization, the collective workplaces of penal institutions or premises where performances or entertainments of any nature are given, without prejudice to the closure of the establishment or premises in question.

Article 19. An offender who by reason of dependence or under the influence of a narcotic drug or substance which causes physical or psychic dependence, as a result of accident or "force majeure", was at the time the act was committed, or omitted, whatever the criminal offence concerned, totally incapable of understanding the unlawful nature of his conduct or of acting on such an understanding shall not be liable to the above penalties.

Sole paragraph. The sentence may be reduced by $^{1}/_{3}$ (one-third) to $^{2}/_{3}$ (two-thirds) if, by reason of any of the circumstances specified in this article, the offender was not, at the time the act was committed or omitted, fully capable of understanding the unlawful nature of his conduct or of acting on such an understanding.

CHAPTER IV

Criminal proceedings

Article 20. The prosecution of the offences created under the present Act shall be governed by the provisions of this chapter, subject to the subsidiary application of the Code of Criminal Procedure.

Article 21. Where a person is arrested "flagrante delicto", the police authority concerned shall notify the competent judge forthwith and transmit the record and a copy thereof to the judge within the following 5 (five) days.

Para. 1. Where there has been no arrest "flagrante delicto", the report of the police investigation shall be transmitted to the court within 30 (thirty) days.

Para. 2. In judicial districts where there is more than one competent jurisdiction, the record or report shall be transmitted as prescribed in the local Judicial Organization Act.

Article 22. Once the above papers are before the court, the Public Prosecutor shall have 3 (three) days in which to lay an information, name witnesses, up to a maximum of 5 (five), and call for such steps as he deems necessary.

Para. 1. For the purposes of drawing up a record of arrest "flagrante delicto" or laying an information, it shall suffice as regards the material fact of an offence if there is an expert statement concerning the nature of the substance involved, signed by an official expert or, failing that, by a suitable person, preferably one who is technically qualified.

Para. 2. Where the statement referred to in the foregoing paragraph is signed by an official expert, he shall not be precluded from taking part in the preparation of the final report.

Para. 3. The information having been laid before the judge, he shall within 24 (twenty-four) hours direct the accused to appear, or order his arrest, and appoint a day and time for the preliminary hearing, which shall take place within the following 5 (five) days.

Para. 4. If the accused cannot be found at the address indicated on the file, the judge shall order him by public proclamation to appear within 5 (five) days, after which he shall be declared in contempt of court. In that case the statutory periods shall run regardless of notice.

Para. 5. At the preliminary hearing, the judge shall question the accused as to whether he is a dependent and point out to him the consequences of his statements.

Para. 6. The accused having been interrogated, the defence shall have 3 (three) days in which to make out a preliminary case, name witnesses, up to a maximum of 5 (five), and call for such steps as it deems necessary. Where there is more than one accused, each of such periods shall run concurrently.

Article 23. Upon the expiry of the period prescribed in paragraph 6 of the preceding article, the judge shall within 48 (forty-eight) hours make an order directing that the necessary steps be taken to try the case and appointing a date within the following 8 (eight) days for the trial and adjudication hearing; this shall be notified to the accused, the testifying witnesses, if any, defence counsel and the prosecution, and also to the police authority and any organs responsible for the transmittal of documents not yet on the file.

Para. 1. In the event of an examination for dependence being ordered, the period within which the hearing must take place shall be 30 (thirty) days.

Para. 2. The hearing shall begin with the questioning of the witnesses, after which counsel for the prosecution and then counsel for the defence shall be called upon to speak for 20 (twenty) minutes each and for an additional 10 (ten) minutes each at the discretion of the judge, who shall then give judgement.

Para. 3. Where the judge considers that he cannot decide the case forthwith, he shall declare the proceedings closed and give judgement within 5 (five) days.

Article 24. Where bail is allowable and the accused is under 21 (twenty-one) years of age, the police authority, if satisfied that he is not in a position to give it, may require him to reside with his parents or relatives or another suitable person, and these shall sign an undertaking.

Para. 1. Any such residence order shall be referred to the competent judge, who may uphold it, revoke it or provisionally release the offender.

Para. 2. If any benefit provided for in this article is withheld, the judge shall order the accused to be committed in custody, subject where applicable to the provisions of article 22, paragraph 4.

Article 25. Records of arrest "flagrante delicto" and reports of police investigations shall be transmitted to the court without prejudice to steps taken to establish the offence, including the preparation of reports on toxicological examinations and, where necessary, on dependence examinations, which reports shall be placed on the file before the trial and adjudication hearing takes place.

Article 26. Registers, documents, items of evidence, records of arrest "flagrante delicto" and reports of police investigations which relate to enquiries into the offences created under the present Act shall be kept under seal and be made available for professional purposes only, at the discretion of the judge, the public prosecutor, the police authority and defence counsel, in accordance with the pertinent legislation.

Sole paragraph. When criminal proceedings are instituted, the seals referred to in the present article may be removed at the judge's discretion.

Article 27. When the offence of trafficking with a foreign country is committed in a municipality which is not the seat of a federal court, it shall be prosecuted and tried by the judicial authorities of the State concerned and the corresponding public prosecutor's department, with a right of appeal to the Federal court of Appeal.

Article 28. Where offences created under the present Act are associated or connected with other criminal offences, the proceedings taken shall be as prescribed for the most serious offence concerned, except in the case of proceedings requiring trial by jury or by a special court.

Article 29. Where the judge finds the accused not guilty, as a result of official expert evidence that his dependence, at the time the act was committed or omitted, made him totally incapable of understanding the unlawful nature of his conduct or of acting on such an understanding, he shall order the accused to undergo medical treatment.

Para. 1. When an offender has been rehabilitated, the fact shall be communicated to the judge, who shall hear official expert testimony to that effect and the opinion of the public prosecutor and then decide whether to close the proceedings.

Para. 2. In the absence of official experts, the offender shall be examined by medical practitioners who shall be appointed by the judge and undertake to discharge their duties well and faithfully.

Para. 3. In the event of an offender failing in any way to co-operate in out-patient treatment or becoming the subject of further proceedings under the circumstances described in the opening provision of this article, the judge may order the offender to be detained in a hospital for treatment.

Article 30. In cases in which bail is allowable, the authority granting or refusing it shall give the reasons for its decision.

Para. 1. Bail shall be fixed by the authority granting it at not less than 500 (five hundred) cruzeiros and not more than 5,000 (five thousand) cruzeiros.

Para. 2. The amounts specified in the foregoing paragraph shall be subject to the application of the monetary indexation coefficient referred to in article 2, sole paragraph, of Act No. 6,205 of 29 April 1975.

Article 31. Where proceedings are instituted against more than one person and a dependence examination is required, the case of the accused who is to undergo the examination shall form the subject of separate and independent proceedings which the judge shall order to be concluded within 30 (thirty) days.

Article 32. Where a person is sentenced to ordinary imprisonment for committing an offence under the present Act, a period of 2 (two) years shall elapse before application may be made for the restoration of his civil rights.

Article 33. Under pain of criminal and administrative liability, senior and other officials and employees of direct and automomous organs of public administration, public enterprises, mixed companies and foundations set up by the public authorities shall give absolute priority to the expert examinations, preparation and issue of documents, publication of proclamations, provision of information and ascertainment of facts required by judicial, legal or administrative authorities for the purpose of instituting proceedings to investigate any of the offences created under the present Act.

Article 34. Vehicles, vessels, aircraft of any other means of transport, and machinery, utensils, instruments or objects of any nature, used in committing offences created under the present Act shall, after due legal seizure, be entrusted to the custody of the competent authority.

Para. 1. If it is possible or necessary to make use of any item mentioned in this article in order to keep it in good condition, the authority having custody of the item may make use of it.

Para. 2. If sentence is passed ordering the confiscation of any such item, it shall become the property of the State.

Article 35. Persons convicted of offences against articles 12 or 13 of the present Act may not be remanded on bail pending appeal.

CHAPTER V

General provisions

Article 36. For the purposes of the present Act, the substances specified in legislation or listed by the National Medical and Pharmaceutical Control Service shall be regarded as narcotic drugs or substances which cause physical or psychic dependence.

Sole paragraph. The National Medical and Pharmaceutical Control Service shall, as circumstances require, review the lists referred to in this article with a view to excluding or including new substances.

Article 37. For the purposes of assessing the gravity of an offence created under the present Act, the authority concerned shall have regard to the nature and quantity of the substance seized, the premises and circumstances in which the offence took place, the circumstances of arrest and the conduct and previous record of the offender.

Sole paragraph. The authority concerned shall make a report giving its reasons for its precise assessment of the offence and mentioning specifically the points referred to in this article, without prejudice to its assessment being altered subsequently by the Public Prosecutor or the judge.

Article 38. Fines shall consist of payment to the National Exchequer of a sum of money calculated in day-fines.

Para. 1. The amount of the day-fine shall be at the discretion of the judge, but not less than 25 (twenty-five) cruzeiros and not more than 250 (two hundred and fifty) cruzeiros.

Para. 2. The amounts specified in the foregoing paragraph shall be subject to the application of the monetary indexation coefficient referred to in article 2, sole paragraph, of Act No. 6,205 of 29 April 1975.

Para. 3. Fines shall be related to the day/fine values prevailing at the time of the offence.

Article 39. The health, police and customs authorities shall compile and maintain statistics, records and other information with regard to their activities for the prevention and suppression of the offences created under the present Act; they shall transmit the same to the competent organ with such comments and suggestions as they deem pertinent to the drafting of the report to be forwarded annually to the International Narcotics Control Board.

Article 40. Any narcotic drug or substance which causes physical or psychic dependence, if seized in connexion with an offence against any provision of the present Act, shall be handed over, once the sentence is no longer appealable, to the competent organ of the Ministry of Health or its state counterpart, which shall be responsible for recording the fact and deciding on the disposal of the drug or substance in question.

Para. 1. The drugs and substances referred to in this article shall be held in the custody of the police authorities until the sentence is no longer appealable.

Para. 2. Where growing plants or an amount difficult to transport or seize in its entirety are involved, the police authority shall take away a sufficient quantity for expert examination, destroy the remainder and prepare a detailed report on its action.

Article 41. The judicial authorities, the public prosecutor and the police authorities may call upon the competent health authorities, irrespective of any legal proceedings, to conduct inspections, at which the requesting authority may be present, of industrial or commercial enterprises, hospital, research, teaching and similar establishments and medical services which produce, sell, purchase, consume or supply narcotic drugs or substances which cause physical or psychic dependence, or any proprietary pharmaceutical preparations containing such drugs or substances.

Para. 1. In the event of the bankruptcy or judicial liquidation of any enterprise or establishment mentioned in this article or of any other enterprise or establishment in which such products exist, the court dealing with the matter shall give notice to the competent health authorities to take immediately the necessary steps to receive on deposit any such products which have been taken into safe keeping.

Para. 2. Any sale by auction of the drugs, substances or proprietary preparations mentioned in this article shall take place in the presence of 1 (one) representative of the competent health authority and bidding shall be confined to authorized natural or juridical persons.

Article 42. An alien who commits any of the offences created under the present Act shall be liable to expulsion under the provisions of the pertinent legislation as soon as he has served the sentence imposed on him, unless the national interest requires that he be expelled immediately.

Article 43. The Courts of Justice shall, wherever necessary and possible, and in accordance with the provisions of article 144, paragraph 5, of the Federal Constitution, set up special courts for the trial and adjudication of the offences created under the present Act.

Article 44. Only police officers who possess appropriate training shall be employed in the narcotics suppression services of the Federal Police Department.

Sole paragraph. The Executive shall provide training for members of the active categories of the Federal Police with a view to implementing the provisions of the present article.

Article 45. Regulations for the implementation of the present Act shall be issued by the Executive within 60 (sixty) days of the publication of the Act.

Article 46. All provisions conflicting with the present Act are hereby repealed, in particular article 311 of Decree Law No. 1004 of 21 October 1969, as amended by Act No. 6016 of 31 December 1973, and Act No. 5726 of 29 October 1971, 1/ with the exception of article 22 thereof.

Article 47. The present Act shall come into force 30 (thirty) days after its publication.

Brasilia, 21 October 1976; the 155th year of Independence and the 88th year of the Republic.

ERNESTO GEISEL

Armando Falcão
Ney Braga
Paulo de Almeida Machado
L.G. do Nascimento e Silva

1/ Note by the Secretariat: E/NL.1973/8

Library of the Court of Criminal Justice of Sao Paulo Federal Legislation

DECREE NO. 78,992 of 21 DECEMBER 1976

Containing regulations pursuant to Act No. 6,368 2/ of 21 October 1976, which promulgates measures for the prevention and suppression of illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence.

The President of the Republic, in exercise of the powers vested in him by article 81(III) of the Constitution and in accordance with the provisions of article 45 of Act No. 6,368 of 21 October 1976, hereby decrees as follows:

Article 1. Every natural and juridical person shall assist in preventing and suppressing illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence.

Para. 1. A juridical person failing to co-operate when requested to do so, in government plans for preventing and suppressing illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence shall forfeit, by decision of the competent organ or authority, any grant or subsidy which it may be receiving from the Union, States, Federal District, Territories or municipalities, or from their autonomous bodies, public enterprises, mixed companies or foundations.

Para. 2. The organ or authority responsible for implementing the plans and programmes of prevention and suppression referred to in article 1, sole paragraph, of Act No. 6,368 of 21 October 1976 shall, upon ascertaining that a juridical person has refused or failed so to co-operate, notify the fact forthwith to the subsidizing authority, which shall within 60 (sixty) days take the necessary steps to the above effect.

Article 2. The planting, cultivation, harvesting and use by private individuals of any plant from which it is possible to extract a narcotic drug or substance which causes physical or psychic dependence shall be prohibited throughout the territory of Brazil.

Para. 1. Wild or cultivated plants of this kind in existence in Brazilian territory shall be destroyed by the police authorities, except in the cases specified in articles 2 and 3 of Act No. 6,368 of 21 October 1976.

Para. 2. Wild or cultivated plants existing in Brazilian territory shall also be destroyed in the event of infringement of any authorization granted under the provisions referred to in this article.

Article 3. The Ministry of Justice may, in addition to reaching agreements with States, request the co-operation of the civil and military authorities of the Union in the destruction of the wild or cultivated plants referred to in paragraphs 1 and 2 of the preceding article.

Article 4. The Ministry of Education and Culture, in conjunction with the Ministry of Health, shall co-ordinate the implementation of the programmes provided for in the opening provision and sole paragraph of article 5 of Act No. 6,368 of 21 October 1976, until such time as the system referred to in article 3 of the aforesaid Act has been established effectively.

Article 5. The ministries of Health and Social Welfare and the Federal Police Department shall within 180 (one hundred and eighty) days issue rules to give effect to articles 8 and 9, and the opening provision and paragraph 1 of article 10, of Act No. 6,368 of 21 October 1976.

Para. 1. For the purposes of the present article, the Ministries of Health and Social Welfare and the Federal Police Department shall made a combined survey of the existing situation in the country with a view to guiding the action of the Federal Government on the problem.

Para. 2. The rules referred in the present article shall cover matters relating to diagnosis and in-patient and out-patient treatment and establish criteria to evaluate the respective requirements of each unit of the Federation.

Article 6. Social welfare activities for dependents undergoing out-patient treatment under article 10, paragraph 1, of Act No. 6,368 of 21 October 1976 shall be directed towards evaluating the influence of social factors on the patient's condition, obtaining a broad view of the clinical picture he presents and improving the planning of therapeutic measures. The activities concerned shall extend to the patient, his family, his place of work and his community, with a view to the success of the treatment and the rehabilitation of the patient.

2/ Note by the Secretariat: E/NL.1978/7.

Article 7. The Ministry of Health shall within 180 (one hundred and eighty) days publish a consolidated version of all the legislative provisions, instructions and lists referred to in articles 6 and 36 of Act No. 6,368 of 21 October 1976 that are in force in regard to the prohibition, restriction, control and supervision of the production, marketing and use of narcotic drugs or substances which cause physical or psychic dependence and of proprietary pharmaceutical preparations containing such drugs or substances.

Article 8. No text, poster, illustration, course, seminar, conference or advertisement on the use of narcotic drugs or substances which cause physical or psychic dependence may be published or held, even as part of a prevention campaign, without the prior authorization of the competent organ.

Article 9. Censorship authorities shall strictly review all public spectacles in order to exclude any scene, situation or display which may, even by implication alone, stimulate interest in the use of narcotic drugs or substances which cause physical or psychic dependence.

Article 10. Licences to plant, cultivate and harvest the plants mentioned in article 2, paragraph 2, of Act No. 6,368 of 21 October 1976 may not be issued except by the National Medical and Pharmaceutical Control Service (NMPCS).

Para. 1. Licences for the activities provided for in the present article shall not be granted except to public juridical persons whose duly attested purpose is the extraction or use of the active principles of the plants referred to in this article for therapeutic or scientific purposes.

Para. 2. An application for a licence shall be submitted by the director or person in charge of the institution concerned, together with the following documents:

I. A full programme or plan of the activities to be undertaken;

II. A list of the technicians who will take part in the activities, with evidence of th qualification for the tasks specified;

III. A complete list of the plants involved, giving their common and modern botanical names, family, genus, species and varieties, if any;

IV. The place and area of the plantation and the estimated production.

Para. 3. Before granting the licence, the National Medical and Pharmaceutical Control Service may require certain steps to be taken or further documents to be submitted.

Para. 4. The National Medical and Pharmaceutical Control Service shall keep the Narcotics Suppression Division of the Federal Police Department informed of the licences it grants.

Para. 5. The National Medical and Pharmaceutical Control Service shall be responsible for ensuring that the terms of the licence are strictly complied with.

Article 11. Whenever plants are destroyed under article 2, paragraph 1, and article 40, paragraph 2, of Act No. 6,368 of 21 October 1976, the destroying authority shall transmit a copy of the relevant report to the National Medical and Pharmaceutical Control Service and to the Narcotics Suppression Division of the Federal Police Department.

Article 12. It shall be within the sole competence of the National Medical and Pharmaceutical Control Service to grant authorizations as provided for in article 2, paragraph 3, of Act No. 6,368 of 21 October 1976, exclusively to juridical persons registered with it beforehand.

Article 13. The distribution in any manner or for any reason, whether to physicians, dental surgeons, veterinarians or pharmacists, of advertising samples of any narcotic drug or substance which causes physical or psychic dependence or of any proprietary pharmaceutical preparation containing such a drug or substance is hereby prohibited; advertisements for such drugs or substances may not appear except in technical and scientific journals or publications restricted in circulation to the members of the above professions.

Sole paragraph. Without prejudice to other legal penalties, any infringement of the prohibition laid down in this article shall be a health offence triable and punishable under Decree Law No. 785 of 25 August 1969.

Article 14. The carriage in transit over Brazilian territory of narcotic drugs or substances which cause physical or psychic dependence shall be subject to a special licence issued by the National Medical and Pharmaceutical Control Service on the application, through the Ministry of Foreign Affairs, of the diplomatic representatives or, failing them, the consular officials of the country to which the drug or substance is to be sent. Such licences shall be issued in duplicate, the original being for the applicant and the copy for the competent organ of the Ministry of Finance.

Sole paragraph. The licence application shall indicate the nature, type and quantity of the drug or substance concerned, the name of the exporting firm, the place of origin, the name of the importer and the country to which the drug or substance is to be sent, and also the places at which it will enter and leave Brazilian territory.

Article 15. Only public organs and institutions authorized beforehand by the National Medical and Pharmaceutical Control Service may receive or donate for therapeutic or scientific purposes narcotic drugs or substances which cause physical or psychic dependence or proprietary pharmaceutical preparations containing them, and may do so only in approved wrappings which duly observe the safeguards required by the Service.

Article 16. Physicians, dentists and veterinarians shall comply rigorously with the laws and regulations relating to the prescription of narcotic drugs and substances which cause physical or psychic dependence.

Article 17. The National Medical and Pharmaceutical Control Service shall be empowered to issue general or special instructions relating to the official prescription forms to be employed for narcotic drugs or substances which cause physical or psychic dependence and to approve specimen forms for statistical returns and balance sheets.

Article 18. All prescriptions, directions for use, labels and wrappings of and for any proprietary pharmaceutical preparation containing a narcotic drug or substance which causes physical or psychic dependence shall bear the following notice prominently displayed in lettering larger than the text:

"WARNING - MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE".

Sole paragraph. The provisions of this article relating to directions for use, labels and wrappings shall be complied with in stages in accordance with a plan prepared by the National Medical and Pharmaceutical Control Service, which shall be ready within 180 (one hundred and eighty) days.

Article 19. Persons in charge of educational or hospital establishments and of social, cultural, recreational, sports and benevolent organizations shall, by common consent and under the technical guidance of specialized authorities, adopt all necessary measures to prevent illicit traffic in and abuse of narcotic drugs or substances which cause physical or psychic dependence near or within the premises in which their activities take place.

Sole paragraph, The aforementioned persons shall be legally and administratively responsible for non-observance of the provisions of this article.

Article 20. The Ministry of Health shall make arrangements for the permanent exchange of information and advice with specialized international agencies and with the health authorities of countries with which Brazil maintains relations. It shall likewise co-operate with domestic organs in the implementation of conventions ratified by Brazil.

Article 21. This decree shall come into force on the date of its publication and all provisions conflicting with it are hereby repealed.

Brasilia, 21 December 1976; the 155th year of Independence and the 88th year of the Republic.

ERNESTO GEISEL

Armando Falcão
Ney Braga
Paulo de Almeida Machado
L.G. do Nascimento e Silva

E/NL.1978/9

ORDER NO. 19 OF 6 SEPTEMBER 1977

The Official in Charge of the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products of the National Secretariat of Health Control of the Ministry of Health, in exercise of the powers vested in him under article 45(III) of Ministerial Order No. 2-RJ of 23 March 1977 and pursuant to article 6 and the opening provision and sole paragraph of article 36 of Act No. 6,368 of 21 October 1976 2/ and article 17 of Decree No. 78,992 of 21 December 1976, 3/ hereby issues the following instructions on the prohibition restriction, control and supervision of the production, trading and use of narcotic drugs and medicines containing such drugs.

3/ Note by the Secretariat: E/NL.1978/8.

CHAPTER I

Narcotic drugs

1. For the purposes of the present Order, the substances listed in schedules I, II and III hereto shall be considered narcotic drugs.

CHAPTER II

Prescription

2. Prescriptions which contain narcotic drugs or medicines containing such drugs may not be dispensed by pharmacies or chemist's shops unless:

(a) They are made out by a legally qualified practitioner;

(b) They are written on an official prescription form conforming to specimen No. 1 annexed to the present Order;

(c) They are written out in full legibly in Portuguese in ink and in the practitioner's own handwriting;

(d) They give the full name and address of the patient and bear the autograph signature of the practitioner, his name in full in legible script, the address of his residence or consulting rooms, his registration number in his professional association and the date of the prescription;

(e) They give the name of the drug or medicine and the dose in legible writing;

(f) The amounts prescribed are given in Arabic numerals and in full;

(g) In the case of an animal, the prescription states the race, species, weight and other characteristics, the place where the animal is kept and the name and address of its owner, in addition to meeting the other requirements specified in this section;

(h) A reason is given for the use of the drug or medicine concerned.

2.1 A block of official prescription forms shall be provided free of charge directly by the competent health authority of the State, Federal District or Territory concerned, against a receipt, to legally qualified practitioners upon application in person or in writing, after completion of the appropriate form with autograph signatures attested by a notary.

2.2 The competent health organs shall keep registers for the purpose of controlling the distribution and supervising the use of blocks of official prescription forms.

3. Prescriptions containing substances specified in section 1 (one) of the present Order shall be written on official prescription forms and be accompanied by a justification for their use, and shall be subject to prior approval and stamping by the competent health authority.

4. The following prescriptions, which shall also be written on official prescription forms and be accompanied by a justification for their use, shall be subject to subsequent approval and stamping and be transmitted within 30 (thirty) days to the competent health authority:

(a) Prescriptions containing substances in schedule I in doses equal to or less than those in schedule A, in which connexion the particulars in the column headed "by injection" shall prevail where the substance is prescribed in its natural state or in mixtures with substances which are either inert or whose action does not preclude parenteral application, either directly or by simple solution;

(b) Prescriptions for medicines in schedule B in the doses indicated therein, where required for emergency use;

(c) Prescriptions for solutions of cocaine hydrochloride in doses up to 1 gram of salt for local anaesthesia in emergency cases.

4.1 The prescriptions specified in this section shall be transmitted under cover of a list in duplicate drawn up in numerical order; one list, duly authenticated by the competent health authority, shall be returned to the pharmacist as proof of delivery. After 30 (thirty) days, on presentation of this document, the validated prescription shall be returned.

5. Official prescription forms and a justification for the use of the substances concerned shall not be required for prescriptions for the following medicines, but the prescriptions in question shall be subject to approval and stamping on the pharmacy's premises by the competent health authority:

(a) Medicines to be taken orally and containing narcotic drugs in schedule I which are associated with other substances that preclude their abuse for non-therapeutic purposes and which are prescribed in doses less than those in schedule A;

(b) Medicines for external topical use containing narcotic drugs prescribed in therapeutic dosage in mixtures with other substances that preclude their abuse for non-therapeutic purposes.

5.1 The prescriptions referred to in this section may not be repeated until 48 (forty eight) hours have elapsed nor more than 3 (three) times.

6. Official prescription forms, a justification for the use of the substance concerned and approval and stamping by the health authorities shall not be required for prescriptions which contain substances in schedule II in therapeutic doses as specified in schedule C.

7. Justifications for the use of narcotic drugs, and prescriptions, shall be sent to the competent health authority in a sealed envelope.

8. In cases of emergency, the medicines referred to in section 4 (four) may be dispensed against prescriptions written on unofficial paper provided that the identity of the purchaser is ascertained and recorded. The prescription shall be submitted to the competent health authority within 24 (twenty four) hours for approval and stamping.

9. Pharmacies shall dispense narcotic drugs in schedule D against prescriptions which comply with the requirements of the Act and the present Order unless there is a good reason to the contrary, in which case it shall be made known in writing to the competent health authority within 24 (twenty four) hours.

10. All allopathic pharmacies shall stock the narcotic drugs listed in schedule D and 3 (three) medicines from schedule B, in injectable form, for emergency cases.

11. Prescriptions containing substances in schedules I and II shall be immediately copied into the prescription book, numbered, initialled by the person in charge and recorded in a register conforming to specimen No. 3 annexed to the present Order. They shall subsequently be filed in the numerical order in which they have been recorded in the prescription book, for inspection, approval and stamping by the competent health authority.

11.1 After approval and stamping, prescriptions and related justifications shall be kept on the premises of the establishment concerned for a period of 5 (five) years, after which they may be destroyed.

12. At the request of the persons concerned, the pharmacist shall provide a true copy of a prescription containing a narcotic drug in schedule II, and shall indicate the number, the date of dispensing and the initials of the person responsible.

13. Prescriptions containing narcotic drugs in schedule I may not be repeated unless they are prescribed afresh medically.

13.1 Prescriptions containing narcotic drugs in schedule II may be repeated upon presentation of the true copy referred to in the preceding section, in which case the pharmacist shall proceed as in the case of the original prescription.

14. The number of the prescription, the name of the patient, the medicine prescribed, instructions for use, the name of the practitioner who prescribed it and the date of dispensing shall be written on the label of the packaging of medicines which are dispensed.

15. Orders for narcotic drugs in their natural form by specialist practitioners shall be subject to the provisions of section 3; the quantity of cocaine hydrochloride prescribed by any dental surgeon shall be limited to 1 (one) gram every 2 (two) months.

15.1 The prescriptions referred to in this section shall be accompanied by a justification for the use of the substance concerned and their approval shall be at the discretion of the competent health authority.

16. Injectable narcotic medication entrusted to the keeping of a physician for emergency use shall be limited to 3 (three) ampoules and may not be replenished without presentation to the competent health authority, for prior approval and stamping, of a prescription stating the name of the patient, the address, the justification for the use of the substance and the date on which the medicine was used.

17. An out-patient medical service may, on application by its director and in his safe keeping and on his responsibility, have up to 3 (three) ampoules of injectable narcotic drugs for use in emergency cases, the prescriptions for which shall be subject to the requirements set out in the preceding section.

18. A written statement by the attending physician justifying an increase in the prescribed dose shall be required for prescriptions for narcotic drugs to be approved before the expiry of the period covered by the medicine previously supplied, as determined by the instructions for use given in the prescription immediately preceding.

19. When there is an interruption in the administration of narcotic drugs to a patient for whom medicines have been prescribed for more than 1 (one) day, the attending physician and the person in charge of the patient shall ensure that the unused narcotic drugs are immediately returned to the competent health authority.

20. The continued use of narcotic drugs in the treatment of illnesses or diseases for which other means of therapy are admissible or recommended shall not be permitted unless it is shown, after a medical discussion attended by the competent health authority, followed by the preparation of minutes of the discussion signed by those present at the meeting and the filing of the minutes in the appropriate office, that the use of the narcotic medicine is indispensable.

21. Except in emergency cases, a physician may not prescribe a narcotic drug for persons belonging to his own family (parents, brothers and sisters, spouse and children) or assume responsibility for treating persons who seek the use of narcotic drugs for medication.

22. The supply of blocks of official prescription forms will be suspended if the practitioner concerned is found to be using them improperly.

23. In public, private or charitable medical or veterinary hospital or para-hospital establishments, narcotic drugs may be supplied to patients on prescriptions which are written on headed yellow hospital prescription forms of the establishment conforming to specimen No. 2 annexed to the present Order and are signed by a practitioner who is on the active staff of the establishment or can show that he is the physician or veterinarian attending the patient concerned.

23.1 Such prescriptions shall give the reason for employing the medicine, the full name of the patient in legible writing, the name of the hospital or para-hospital establishment and the number of the ward, room or bed occupied by the patient, in addition to meeting the requirements laid down in subsections (a), (c), (e), (f) and (q) of section 2 of the present Order, and may not be dispensed outside the establishment itself.

23.2 The prescription referred to in this article may be dispensed without the prior or subsequent approval of the competent health organ, which approval shall be replaced by that of the competent health authority on its visits of inspection.

23.3 The director of the establishment concerned shall be responsible for the internal control of the use of the narcotic drugs in question.

23.4 In the medical dispensary of establishments using narcotic drugs, there shall be employed and made responsible a legally qualified pharmacist or other practitioner. In the absence of such a person, the physician or veterinarian officially responsible for the establishment shall be the custodian and person responsible for the control and supervision of the use of such drugs.

24. In public, private or charitable medical or veterinary hospital or para-hospital establishments, whether or not these establishments have their own dispensary, the senior physician or veterinarian on duty may, on application to the director by the head physician or veterinarian, have three units of narcotic drugs in his keeping in injectable form for emergency cases.

24.1 In order to keep a check on the quantities supplied, the quantity originally applied for shall be replenished on presentation of the appropriate prescription on a hospital prescription form, subject to compliance with the other requirements laid down in the present Order.

RECORDS

25. All operations relating to narcotic drugs shall be recorded in a register conforming to specimen No. 3 annexed to the present Order on the day of the operation itself and by the person in charge of the establishment concerned.

25.1 The competent health authority shall mark the register to record its opening and closing and shall initial each page.

25.2 Each page of the register shall be used to record one substance or medicine only.

25.3 All operations relating to the substances and medicines concerned shall be recorded meticulously, legibly and without alterations (amendments, erasures, blemishes or interlineations).

25.4 Corrections shall be made in the section headed "Comments".

26. Establishments which dispense prescriptions containing a narcotic drug shall, immediately after dispensing them, copy the prescription into the prescription book and record it in the register.

26.1 Prescriptions containing narcotic drugs listed in schedule II may be recorded in shortened form with the name and and address of the patient, and the name of the physician, omitted, and more than one entry may be made on the same line.

26.2 After being recorded, prescriptions and justifications for their use, where applicable, shall be filed in chronological order in the establishment concerned for inspection and approval by the competent health authority.

26.3 After approval, prescriptions and justifications for their use shall be kept on file in the establishment concerned for five (5) years, after which they may be destroyed.

27. Issues of the narcotic drugs or medicines concerned in the form of sales shall be recorded by giving the following details: in the "PARTICULARS" column, the name and address of the buying enterprise and the form in which the drug or medicine was sold; in the column which follows the "STOCK" column, the name of the person responsible in the buying establishment; in the remaining columns, the details required for dispensing the prescription.

28. Issues of the substances concerned for use in the manufacture of preparations in the establishment itself shall be recorded by giving the following details: in the "PARTICULARS" column, the name and quantity of the preparation to be manufactured, and in the "COMMENTS" column the liquid volume of the batch (after sterilizing, filtering, bottling, etc.). The remaining columns shall be completed in the same way as for other issues.

29. Each entry in the register shall be matched in the files of the establishment by a voucher duly authenticated by the competent health authority: in the case of receipts, the clearance permit for narcotic drugs or substances causing physical or psychic dependence or the order form; in the case of issues, the order form or the medical prescription. Issues of substances for the manufacture of preparations shall be balanced by entries showing the receipt into stock of the batch concerned.

30. The vouchers in question shall be kept on file separately: receipt vouchers in date order, prescriptions in the order of their entry number in the prescription book and sales vouchers in alphabetical order of the buyer's name and in date order for each buyer.

30.1 The following documents shall vouch for the legality of entries recording the various operations connected with the drugs and medicines to which the present Order refers: order forms, return notes, clearance permits for narcotic drugs or substances causing physical or psychic dependence, fiscal vouchers, registers, import vouchers, monthly sales statements and quarterly or annual balance sheets.

31. In hospitals and para-hospital establishments and in medical and veterinary services which do not have their own dispensaries, prescriptions for narcotic preparations and medicines shall be recorded as indicated in the opening provision and subsections of section 26, with the exception that only the name and place of stay of in-patients and the addresses of day patients and out-patients shall be entered in the "PARTICULARS" column.

32. In research and teaching establishments, requests for narcotic drugs and medicines shall be recorded immediately after supply to the research worker concerned, the purpose and justification being entered under "PARTICULARS" and the name of the person requesting the substance being given in the column following the "STOCK" column.

TRADE

33. Purchases of narcotic drugs and medicines by pharmaceutical, hospital, para-hospital, research and teaching establishments shall not be made except by means of order forms validated by the competent health authority of the State, Federal District or Territory and in compliance with the following requirements:

(a) Orders shall be written legibly in Portuguese without erasures or alterations on printed forms conforming to specimen No. 4 annexed to the present Order and shall state the designation, name and address and name of the person responsible, as regards the buying establishment, the designation, name and business address of the selling establishment, the precise description of the drugs and medicines involved and their packaging and the quantities in Arabic numerals and in full;

(b) Lines on the order form which are not filled in shall be ruled through;

(c) Orders shall be in sextuplicate where both the buying and selling establishments are in the same State, in the Federal District or in the same Territory and in octuplicate where they are in different units of the Federation.

34. Orders shall first be taken by the seller for approval and stamping to the competent local health authority responsible for supervising the buying establishment, and subsequently, if the buyer and seller are located in different units of the Federation, the orders shall be taken to the competent health authority for the place in which the seller is located.

34.1 In filling in the order forms, the buying establishment shall state in the "Comments" column or on the back of the form the stocks held on the date of ordering and the average monthly consumption over the previous 12 (twelve) months.

34.2 Order form approvals shall be valid for a period of 60 (sixty) days from the date on which they are given by the competent local health authority for the place in which the buying establishment is situated, and shall expire automatically at the end of that period.

34.3 Where both the buying and selling establishments are in the same State, in the Federal District or in the same Territory, the competent health authority shall retain two copies of the order form for control purposes and return the remaining copies to the seller duly validated, stamping one of them with the words "consignment note", to be handed to the buyer with the goods; one copy shall be retained by the seller, who shall file it as a sale voucher, and the remaining two copies shall be forwarded by the seller to the Narcotic Drugs Suppression Service of the Federal Police Department.

34.4 Where the buying and selling establishments are not both in the same State, in the Federal District or in the same Territory, in addition to the requirements of the preceding subsection being met, the seller shall forward the two additional copies of the form respectively to the competent health authority and to the Narcotic Drugs Suppression Service of the Federal Police Department for the unit of the Federation in which the establishment is situated.

35. Supervisory health authorities shall not, without the express authorization of the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED), approve orders which would bring stocks up to amounts greater than the requirements for 6 (six) months.

35.1 To obtain the concession mentioned in this section, the person concerned shall, in the "Comments" section or on the back of the order form, state the remaining stocks and the average monthly consumption over the previous 12 (twelve) months.

36. Estimates of the initial minimum stock required by each establishment shall be at the discretion of the competent health authority of the State, Federal District or Territory concerned.

37. Only the competent health authorities of States, the Federal District or Territories may alter or amend orders, and in such a case they shall validate the change clearly on the form and report the matter, together with the reasons for the change, to the competent health authority which earlier approved the order.

38. Narcotic drugs or medicines shall be returned by the buyer to the seller in the following manner:

(a) The buyer shall submit to the competent local health authority a statement giving his reasons for wishing to return the goods concerned, accompanied by 6 (six) or 8 (eight) copies, as the case may be, of a printed return note conforming to specimen No. 4, but with the words "ORDER FORM" replaced by the words "RETURN NOTE";

(b) If the reasons are accepted, the return shall take place in the same manner as the purchase and in accordance with the provisions of sections 33(a), (b) and (c), 34, 34.3 and 34.4 of the present Order;

(c) The seller shall inform the competent local health authority when he receives the returned goods.

39. Sales shall not take place except on presentation of order forms validated by the competent health and police authorities and the entire order concerned shall be delivered at one and the same time.

40. Failure to comply with the requirements set out in the opening provision and subsections of section 33 and in sections 34, 34.3, 37 and 39 shall entail suspension of approval for orders in which the offending establishment appears as buyer or seller.

41. In the event of the register or any narcotic drugs and/or medicines referred to in the present Order being impounded on the premises of any pharmaceutical, hospital, para-hospital, research or teaching establishment by order of the Government or the courts, the establishment concerned shall be barred from using the said drugs and/or medicines until a new register, authenticated by the competent health authority, has replaced the impounded register.

42. The import, export and re-export of the drugs and medicines referred to in the present Order shall be subject to authorization by the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED).

43. For the purposes of the preceding section, the person concerned, duly authorized to deal with the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED), shall apply for an import, export or re-export certificate and authorization.

44. If the application is granted, 7 (seven) copies of a non-transferable import certificate, shall be issued, for the following recipients:

First copy: National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED);

Second copy: importer;

Third copy: exporter;

Fourth copy: competent authority of the exporting country;

Fifth copy: Narcotic Drugs Suppression Service of the Federal Police Department in Rio de Janeiro;

Sixth copy: National Commission for the Control of Narcotic Drugs (CONFEM);

Seventh copy: The competent health authority of the State, Federal District or Territory.

44.1 The import certificate shall be valid only for the year for which it is granted.

45. Seven copies of the import authorization shall be issued with the import certificate, for the same recipients as listed in the previous section.

46. Narcotic drugs and medicines containing them may not enter Brazilian territory except through the competent Federal Revenue Inspectorate of the State of Rio de Janeiro and on production for each consignment of 4 (four) copies of a clearance permit conforming to specimen No. 10 annexed to the present Order.

46.1 For this purpose, the person concerned shall submit to DIMED a commercial invoice for each consignment, giving full details of the name, nature, place of origin and quantity of the goods in question and the year and quarter to which the import authorization relates, to enable the clearance permit to be validated for removal of the goods from the Federal Revenue Inspectorate.

47. The requirements laid down in the present Order shall apply to importers where appropriate.

MONTHLY SALES STATEMENTS

48. The persons in charge of enterprises and establishments conducting any activity whatsoever contributing towards the production and/or marketing of the drugs and medicines to which the present Order refers shall, before the tenth working day of each month, forward to the competent local health authority a statement of the sales made during the preceding month to other enterprises or establishments or hospital, para-hospital, research or teaching bodies.

48.1 The statements shall be prepared as follows on printed forms conforming to specimen No. 5 annexed to the present Order: the drugs and medicines concerned shall be listed in the order in which they appear in schedules I, II and B; the amounts shall be given in Arabic numerals and in full and the form in which the substances were supplied shall be indicated; the dates of dispatch and of approval by the local health department, the names of the buying enterprises or establishments or hospital, para-hospital, research or teaching bodies and the names and addresses of the persons respectively responsible for them at law shall be shown.

QUARTERLY BALANCE SHEETS

49. The persons in charge of enterprises or establishments conducting any and every activity contributing towards the production and/or marketing of the drugs and medicines listed in schedules I, II and B to the present Order shall, before the tenth working day of the months of January, April, July and October, forward to the competent local health authority two copies of a quarterly balance sheet prepared on printed forms conforming to specimens Nos. 6 or 7 annexed to the present Order and showing the amounts acquired, sold, used and held in stock; one copy, duly authenticated, shall be returned to the person concerned with proof of delivery.

50. For the quarterly balance sheets, the specimens mentioned in the preceding section shall be used by dispensing and industrial establishments and by chemist's shops, distributors, exporters and agents respectively.

ANNUAL BALANCE SHEETS

51. Pharmaceutical establishments of every kind shall, before the 10th (tenth) day of January each year, forward to the competent local health authority two copies of an annual balance sheet conforming to the specimens prescribed in section 50 and to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) one copy thereof.

51.1 The provisions of this section shall apply to public, private and charitable medical and veterinary hospital and para-hospital establishments and to research and teaching establishments.

51.2 The pharmacies and establishments referred to in the preceding subsection shall not be required to send a copy of their annual balance sheet to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED).

52. Persons in charge of public, private and charitable medical and veterinary hospital and para-hospital establishments shall, wherever there is any consumption of the drugs and medicines listed in schedules I, II and B, forward to the competent local health authority before the 10th (tenth) day of each month two copies of a monthly statement of use conforming to specimen No. 8 annexed to the present Order. One copy shall be authenticated and then returned to the person concerned as proof of delivery. Research and teaching establishments shall use specimen No. 9 annexed to the present Order.

53. Failure to submit the required statements and balance sheets within the specified period or their submission with erasures, alterations or errors shall result in suspension of approval for orders for drugs and medicines listed in schedules I, II and B in which the offending establishment appears as buyer or seller.

AUTHORIZATION

54. Any enterprise that extracts, produces, manufactures, processes, prepares, possesses, imports, exports, re-exports, dispatches, transports, displays, offers, sells, buys, exchanges, transfers or acquires for any purpose a narcotic drug or a raw material intended for the preparation of a narcotic drug shall obtain a special authorization from the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials, Dietetic and Related Products (DIMED), and comply with the other requirements of the law, before embarking on any of the above operations.

55. On the cessation of any of the operations enumerated in the previous section, the persons responsible for the enterprises concerned shall take an inventory of their remaining stocks within 30 (thirty) days and surrender them to the competent health authority for suitable disposal.

PACKAGING

56. Packaging for narcotic drugs and medicines shall be such that it cannot be tampered with and that the substances concerned are easily identifiable.

57. The labels and packagings of medicines containing narcotic drugs shall have a horizontal black band encircling the middle third of the entire package, equal in width to not less than one third of the length of the longer side of the main face, and bearing the words "To be sold on medical prescription" and "Warning - may cause physical or psychic dependence".

57.1 Instructions for use of the medicines referred to in this section shall carry clearly and in lettering larger than the text the words "WARNING - MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE".

58. The medicines listed in schedule B to the present Order shall be labelled and packaged as follows:

(a) Injectable preparations shall have their name printed on the bottle and be put up in ampoules containing one unit, with a safety seal or other device to prevent tampering, and packed in boxes containing 5 (five) ampoules when intended for sale to the public and in special packages of 25 (twenty-five), 50 (fifty) or 100 (one hundred) one-unit ampoules when intended for use by hospital and para-hospital organizations or for retail sale by pharmacies on medical prescription.

(b) Medicines in solid form (tablets, dragees, capsules, pills and suppositories) shall be put up in distinctive packaging in amounts of 10 (ten) dosage units.

58.1 The medicines Fentanyl 4/ and Innovar may be packaged in ampoules or phials of 2 (two) and 10 (ten) millilitres.

4/ Note by the Secretariat: International non-proprietary names are underlined.

59. The sale of the drugs or medicines covered by the present Order in any of the packagings mentioned in the various subsections of the preceding section shall not be permitted if the printed material does not comply with the requirements of sections 56, 57 and 57.1.

60. An enterprise which is the registered owner of a medicine containing in its formula a substance listed in schedule I shall have 60 (sixty) days from the date of publication of the present Order in which to submit to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) designs of specimen labels showing their proposed size and giving instructions for use and packaging which comply with the provisions of the present Order.

61. The failure of medicines at present in establishments to comply with the provisions of sections 56, 57, 57.1 and 59 shall not constitute a health offence if the medicines were acquired before the date of publication of the present Order.

GENERAL PROVISIONS

62. The distribution of samples of drugs and medicines covered by the present Order is prohibited, whether to doctors, dentists, veterinarians and pharmacists or otherwise.

63. Any drugs and medicines covered by the present Order which are seized in connexion with the infringement of any of its provisions shall be handed over by the seizing authority to the competent health authority of the State, Federal District or Territory where the seizure took place, and a detailed report on the occurrence shall be made to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED).

64. Advertisements for drugs or medicines covered by the present Order may not appear except in technical and scientific journals or publications the circulation of which is confined to physicians, dentists, veterinarians and pharmacists.

65. In the event of the bankruptcy or judicial liquidation of any establishment referred to in the present Order, the competent health authority shall arrange for the receipt on deposit of any stocks taken into safe keeping or forming part of the liquidation assets, on notice from the court dealing with the proceedings.

66. No sale by judicial auction of drugs and/or medicines covered by the present Order shall take place without the presence of a representative of the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) or a related health organ empowered by the Service, and bidding shall be confined to natural or juridical persons lawfully authorized by the competent health authority.

67. The competent health authorities of the Army, Navy and Air Force shall, in addition to complying with those provisions of the present Order which are applicable to the health services within their competence, forward annually to the competent health authority general balance sheets showing receipts, consumption and stocks of the substances and/or medicines covered by the present Order, in conformity with the requirements thereof.

68. The competent health and police authorities shall assist each other in any steps required to ensure strict compliance with the provisions of the present Order and shall observe secrecy in their investigations.

69. Failure to comply with the requirements of the present Order shall be a health offence rendering the offender liable to prosecution and punishment under Act No. 6,437 of 20 August 1977, without prejudice to any other penalty, civil or criminal, to which he may be liable.

70. 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.

71. The present Order shall come into force on the day of its publication.

72. Orders Nos. 1 of 19 February 1963, 20 of 21 September 1965 and 3 of 8 May 1967 of the former National Medical and Pharmaceutical Control Service and the General Instructions on the Use and Marketing of Narcotic Drugs published in the Official Journal of the Union of 23 May 1939 are hereby repealed, together with any other conflicting provisions.

Fernando Ayres da Cunha

SCHEDULE I

Narcotic drugs

Acetorphine 4/

Acetylmethadol

Allylprodine

Alphacetylmethadol

Alphameprodine

Alphamethadol

Alphaprodine

Anileridine

Benzethidine

Benzylmorphine

Betacetylmethadol

Betameprodine

Betamethadol

Betaprodine

Bezitramide

Cannabis (resin, extracts and tinctures)

Clonitazene

Coca leaf

Cocaine

Codoxime

Concentrate of poppy straw (the material arising when poppy straw has entered into a process for the concentration of its alkaloids)

Desomorphine

Dextromoramide

Diampromide

Diethylthiambutene

Difenoxin

Dihydromorphine

Dimenoxadol

Dimepheptanol

Dimethylthiambutene

Dioxaphetyl Butyrate

Diphenoxylate

Dipipanone

Drotebanol

Ecgonine (its esters and derivatives which are convertible to ecgonine and cocaine)

Ethylmethylthiambutene

Etonitazene

Etorphine

Etoxeridine

Fentanyl

Furethidine

Heroin

Hydrocodone

Hydromorphinol

Hydromorphone

Hydroxypethidine

Isomethadone

Ketobemidone

Levomethorphan (dextromethorphan and dextrorphan are excluded from this schedule)

Levomoramide

Levophenacylmorphan

Levorphanol

Metazocine

Methadone

Methadone intermediate (4-cyano-2-dimethylamino-4-diphenylbutane)

Methyldesorphine

Methyldihydromorphine

Metopon

Moramide intermediate (2-methyl-3-morpholino-1,1-diphenylpropane carboxylic acid)

Morpheridine

Morphine

Morphine methobromide (and other pentavalent nitrogen morphine derivatives, especially morphine-N-oxide derivatives)

Morphine-N-oxide

Myrophine

Nicomorphine

Noracymethadol

Norlevorphanol

Normethadone

Normorphine

Norpipanone

Opium

Oxycodone

Oxymorphone

Pethidine

Pethidine intermediate A (4-cyano-1-methyl-4-phenylpiperidine)

Pethidine intermediate B (4-phenylpiperidine-4-carboxylic acid ethyl ester)

Pethidine intermediate C (1-methyl-4-phenylpiperidine carboxylic acid)

Phenadoxone

Phenampromide

Phenazocine

Phenomorphan

Phenoperidine

Piminodine

Piritramide

Proheptazine

Properidine

Racemethorphan

Racemoramide

Racemorphan

Thebacon

Thebaine

Trimeperidine

The isomers, unless specifically excepted, of the drugs in this schedule whenever the existence of such isomers is possible within the specific chemical designation.

The esters and ethers, unless appearing in another schedule, of the drugs in this schedule whenever the existence of such esters or ethers is possible.

The salts of the drugs listed in this schedule, including the salts of esters, ethers and isomers as provided above whenever the existence of such salts is possible.

SCHEDULE II

Narcotic drugs

Acetyldihydrocodeine

Codeine

Dihydrocodeine

Ethylmorphine (dionine)

Nicocodine (6-nicotinylcodeine)

Nicodicodine (6-nicotinyldihydrocodeine)

Norcodeine

Pholcodine

Propiram

The isomers, unless specifically excepted, of the drugs in this schedule whenever the existence of such isomers is possible within the specific chemical designation.

The salts of the drugs listed in this schedule, including the salts of the isomers whenever the existence of such salts is possible.

SCHEDULE III

Narcotic drugs

Cannabis and cannabis resin, ketobemidone

Desomorphine

Heroin

The salts of the drugs listed in this schedule whenever the existence of such salts is possible.

SCHEDULE A

Narcotic drugs

Substance	By mouth	By injection
Raw opium or powdered opium	0.60 g	-
Extract of opium	0.30 ml	-
Liquid extract of opium	0.60 ml	-
Tincture of opium	10 ml	-
Sydenham's laudanum	10 ml	-
Rosseau's laudanum	3 ml	-
Syrup of opium	120 ml	-
Morphine and its salts	0.10 g	0.03 g
Syrup of morphine	100 ml	-
Dilaudid (hydromorphone) and its salts	0.025 g	0.006 g
Dicodid (dihydrocodeine) and its salts	0.05 g	0.045 g
Cocaine and its salts	0.10 g	0.02 g
Meperidine	-	0.10 g
Methadone	0.01 g	0.01 g

SCHEDULE B

Narcotic medicines

NAME	Dose referred to in section 4 (b) of the Order	
	By injection	Tablets
Belacodid	5 ampoules	-
Codeine (injectable solution)	5 ampoules of 0.02 g	-
Demerol	3 ampoules	10 tablets
Dilaudid	3 ampoules	10 tablets
Dilaudid with atropine	3 ampoules	-
Dilaudid with scopolamine	3 ampoules	-
Dolantin	3 ampoules	10 tablets
Dolcsona	3 ampoules	10 tablets
Dorexol	3 ampoules	10 tablets
Lipomorfin	3 ampoules	-
Morphine - injectable solution	3 ampoules of 0.01 g	-
Morphine - injectable solution	1 ampoule of 0.02 g	-
Pethidine solution	3 ampoules	-

	By injection	Tablets
Pethidine solution with hyoscine	3 ampoules	-
Prenarcol	3 ampoules	-
Phenylcodeine	5 ampoules	-
Spasmodolisina	3 ampoules	10 tablets 10 suppositories
Tebatropin	5 ampoules	-

EXCLUSIVELY FOR HOSPITAL USE (AS ANAESTHETICS)

Fentanyl

Innovar

SCHEDULE C

1. Preparations of:

Acetyldihydrocodeine

Codeine

Dihydrocodeine

Ethylmorphine

Nicodicodine

Norcodeine

Pholcodine

when compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5 per cent in undivided preparations.

2. Preparations of propiram containing not more than 100 milligrams of propiram per dosage unit and compounded with at least the same amount of methycellulose.

3. Preparations of cocaine containing not more than 0.1 per cent of cocaine calculated as cocaine base and preparations of opium or morphine containing not more than 0.2 per cent of morphine calculated as anhydrous morphine base and compounded with one or more other ingredients and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

4. Preparations of difenoxin containing, per dosage unit, not more than 0.5 milligram of difenoxin and a quantity of atropine sulphate equivalent to at least 5 per cent of the dose of difenoxin.

5. Preparations of diphenoxylate containing, per dosage unit, not more than 2.5 milligrams of diphenoxylate calculated as base and a quantity of atropine sulphate equivalent to at least 1 per cent of the dose of diphenoxylate.

6. Pulvis ipecacuanhae et opii compositus

10 per cent opium in powder

10 per cent Ipecacuanha root, in powder well mixed with

80 per cent of any other powdered ingredient containing no drug.

7. Preparations conforming to any of the formulae listed in this schedule and mixtures of such preparations with any material which contains no drug.

SCHEDULE D

List of narcotic drugs which must be carried by the pharmacies referred to in section 10 of Order No. 19/77

SUBSTANCE	Minimum quantity for pharmacy outfit	Amount below which stocks must not fall
Extract of opium	25 g	5 g
Liquid extract of opium - 100% - Brazilian pharmacopoeia	50 ml	20 ml
Powdered opium	25 g	10 g
Tincture of opium	100 ml	40 ml
Tincture of opium with saffron	100 ml	40 ml
Morphine hydrochloride	4 g	1 g
Morphine hydrochloride, 0.01 g ampoules	6 ampoules	3 ampoules
Idem, 0.02 g ampoules	6 ampoules	3 ampoules
Cocaine hydrochloride	2 g	1 g
Dionin	4 g	1 g
Pure codeine	4 g	1 g
Codeine phosphate	8 g	3 g
Choice of three proprietary injectable preparations from schedule B	1 box of each	3 ampoules of each

Specimen 1

Official prescription form

5 cm

Competent department of the State, Federal District or Territory

No.

Name of patient .....

Address .....

Date .....

7 cm

No.

JUSTIFICATION FOR USE

Name of patient .....

Address .....

Signature .....

Practitioner's registration number .....

Residence or consulting rooms .....

Date .....

15 cm

Competent department of the State, Federal District or Territory

BLOCK OF OFFICIAL PRESCRIPTION FORMS

No.

WARNING: MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE

Name of patient .....

Address .....

Signature .....

Practitioner's registration number .....

Residence or consulting rooms .....

Date .....

93 mm

Specimen No. 2

Block of hospital prescription forms

Narcotic medicines

12 cm

7 cm

Hospital prescription form

Form No. (printed)

Name and type of establishment

Official responsible

Address

Name of patient

Nurse Bed

Ward

Out-patient

Use

Medicine
(hospital voucher)

Signature

Practitioner's registration number

Warning: May cause physical or psychic dependence

To be printed on pale yellow paper

12 cm

Specimen 3 - back

28 cm

Date			Particulars	Movements			Stock		Comments
Day	Month	Year		Receipts	Issues	Losses			
1 cm	1 cm	1 cm	---13 cm ---	----------	6.5 cm	-------	------	4.5 cm	4 cm
----	3 cm	------	lines 7 mm apart	1.5 cm	1.5 cm	1.5 cm	2 cm		

Specimen 3

28 cm

Date			Particulars	Movements			Stock		Comments
Day	Month	Year		Receipts	Issues	Losses			
1 cm	1 cm	1 cm	---13 cm ---	----------	6.5 cm	-------	------	4.5 cm	4 cm
----	3 cm	------	lines 7 mm apart	1.5 cm	1.5 cm	1.5 cm	2 cm		

Specimen 4

Order forms (narcotic drugs and medicines and substances causing physical or psychic dependence)

ORDERED BY .....

(name of person responsible)

ON BEHALF OF .....

(name of establishment or enterprise)

SITUATED AT .....

(address)

FROM .....

(name of establishment or enterprise)

SITUATED AT .....

(address)

SUBSTANCE OR MEDICINE	QUANTITY
9 cm	9 cm

.....19....

.....

Signature of person legally responsible

COMMENTS	APPROVAL STAMP (of competent health authority)	Rubber stamp of buyer
6 cm	8 cm	4 cm

12 cm + 2 cm + 5 cm = 20 cm

27 cm

The back of this form shall be left blank.

Length of form 40 cm

Specimen 5 Rubber stamp to enterprise and signature of its legal representative	MONTHLY SALES STATEMENT (NARCOTIC DRUGS AND MEDICINES AND SUBSTANCES CAUSING PHYSICAL OR PSYCHIC DEPENDENCE) Month of .....19..... ..... (name of enterprise or establishment) ..... Enterprise	Received on ..... Checked by .....

HEAD OFFICE .....

(Full address: street and No., city, municipality, State)

SIGNATURE OF OFFICIAL RESPONSIBLE .....

Substance or medicine	Quantity	Day	Date of approval	BUYER		
				Enterprise or establishment	Legal representative	Full address
6 cm	4 cm (ruled)	1 cm	2 cm	5 cm	5 cm	10 cm

The back shall be left blank.

Specimen 6

Rubber stamp of establishment or enterprise and signature of its legal representative

QUARTERLY)
ANNUAL) BALANCE SHEET (NARCOTIC DRUGS AND MEDICINES AND SUBSTANCES CAUSING PHYSICAL OR PSYCHIC DEPENDENCE)

From ..... 19 ... to ..... 19 ...

.....
(Name of pharmacy or establishment)

.....
(Enterprise)

Received on .....

Checked by

on.....

HEAD OFFICE .....
(Full address: street and No., city, municipality, State)

SIGNATURE OF OFFICIAL RESPONSIBLE.....

Length of form 40 cm

Substance or medicine	Stock at beginning of period	Receipts (acquisition or preparation)	Issues (sales, prescription forms)	Internal consumption (manufacture of preparations or medicines)	Losses (bottling, evaporation, deterioration, breakages)	Balance at end of period	Preparations or medicine with substance			Comments
							Name	Quantity manufacture	Substance consumed in manufacture	
6.5 cm	2 cm	2 cm lines 7 mm apart	2 cm	2 cm	2 cm	2 cm	5.5 cm	2 cm	2 cm	5 cm

Specimen 7

Length of form 40 cm

Rubber stamp of enterprise and signature of its legal representative	QUARTERLY) ANNUAL) BALANCE SHEET (NARCOTIC DRUGS AND MEDICINES AND SUBSTANCES CAUSING PHYSICAL OR PSYCHIC DEPENDENCE) From ..... 19 ... to ..... 19 ... . Name of chemist's shop, distributor, importer, exporter or agent ..... Enterprise	Received on ..... Checked by on .....

HEAD OFFICE .....
(Full address: street and No., city, municipality, State)

SIGNATURE OF OFFICIAL RESPONSIBLE .....

Substance or medicine	Stock at beginning of period	Receipts (acquisition)	Issues (sales)	Losses (deterioration, breakages)	Balance at end of period	Comments
12 cm (ruled)	28 cm	28 cm	28 cm	28 cm	28 cm	6 cm

Specimen 8

Rubber stamp of establishment and signature of its director	MONTHLY STATEMENT OF USE (NARCOTIC DRUGS AND MEDICINES AND SUBSTANCES CAUSING PHYSICAL OR PSYCHIC DEPENDENCE) Hospital establishment ..... Address ..... Year ..... Month ..... Signature of medical official responsible ..... Practitioner's registration number	Received on ..... Checked by on .....

44 cm

Day	Name of patient	Medication prescribed	No. of entry in prescription book	Attending physician	Justification for use
1 cm	8 cm	7 cm (ruled)	2 cm	7 cm	2 cm

Specimen 8 - back

23 cm

Day	Name of patient	Medication Prescribed	No. of entry in prescription book	Attending physician	Justification for use
		(ruled)			

SUMMARY OF MOVEMENTS IN THE MONTH OF .....

Substance or medicine	Previous balance	Receipts	Issues	Losses	Current balance	Comments
(ruled) 12 cm	(ruled) 23 mm	(ruled) 23 mm	(ruled) 28 mm	(ruled) 28 mm	(ruled) 28 mm	(ruled) 6 cm

21 cm

.....
Signature of pharmacist or director responsible for the hospital establishment, practitioner's association.

Specimen 9

Rubber stamp of establishment or enterprise and signature of its legal representative	MONTHLY STATEMENT OF USE (NARCOTIC DRUGS AND MEDICINES AND SUBSTANCES CAUSING PHYSICAL OR PSYCHIC DEPENDENCE) Establishment or enterprise ..... Address ..... Year ..... month ..... Signature of official responsible	Received on ..... Checked by on .....

Substance or medicine	Justification for use	Quantity	Consumer	Day
9 cm	9 cm	3 cm	9 cm	2 cm

44 cm

Specimen 9 - back

Substance or medicine	Justification for use	Quantity	Consumer	Day

23 cm

SUMMARY OF MOVEMENTS IN THE MONTH OF .....

Substance or medicine	Previous balance	Receipts	Issues	Losses	Current balance	Comments
(ruled) 12 cm	(ruled) 28 mm	(ruled) 28 mm	(ruled) 28 mm	(ruled) 28 mm	(ruled) 28 mm	(ruled) 6 cm

21 cm

.....
Signature of official responsible

Specimen 10

32 cm

20.5 cm

No. _____ _____ copy

CLEARANCE PERMIT (NARCOTIC DRUGS OR SUBSTANCES CAUSING PHYSICAL OR PSYCHIC DEPENDENCE)

IMPORTER .....

EXPORTER .....

PORT OF SHIPMENT ..... COUNTRY OR ORIGIN .....

AIRPORT OF SHIPMENT ..... VESSEL ..... LEFT ON ..... ENTERED ON .....

AIRCRAFT .....

COMMERCIAL INVOICE NO. ..... of .....

BILL OF LADING NO. ..... of .....

DIMED/MH IMPORT AUTHORIZATION NO.

WAREHOUSE NO. ..... GATE .....

APPROVAL STAMP OF THE BRAZILIAN CONSULATE AT .....

..... dated .....

RELATED CERTIFICATE NO. ..... of .....

CUSTOMS CLEARANCE DOCUMENT NO. ..... of .....

1 cm 1 cm

PACKAGES					
Marks	No.	Quantity	Type	Gross Weight	
	2.4 cm	12 cm			SPECIFY substance(s), amount(s) in full and by net weight DESCRIBE the packaging (see note III overleaf)
					20 cm

7.2 cm

Rubber stamp of importing enterprise 12 cm	Rio de Janeiro, ... 10 cm ..... Signature of responsible official of importer	Rio de Janeiro 10 cm ..... Rubber stamp and signature of customs agent

4 cm

20.4 cm

10 cm

NOTES

I. Importers established in Rio de Janeiro/RJ should submit three copies of this permit to DIMED/MH, Control and Supervision Section, for approval and stamping.

The top copy will be kept on file in the Control and Supervision Section of DIMED/MH; the second will be attached to the customs clearance document; the third will serve as a consignment note, accompanying the goods to their destination and remaining in the possession of the importer, who will file it as his import voucher. Four copies will be required for importers established outside the State of Rio de Janeiro; the third copy will continue to serve as a consignment note and the fourth copy will be sent by DIMED/MH to the competent health authority at the place of destination.

II. Commercial invoices and aircraft bills of lading must be shown to the Control and Supervision Section of DIMED/MH when the permit form is submitted for approval.

III. The permit form must be completely filled in, accurately and clearly and in full, and without erasures, alterations or blemishes. It must state the precise nature of the substance(s), the amount(s), the total net weight (liquid) of each substance, the nature and quantity of the packaging, the place of origin, where required (coca leaf and raw opium), and the exporter(s) of the imported substance(s).

7.3 cm

APPROVAL STAMP OF DIMED/MH 10.2 cm	APPROVAL STAMP of the Federal Revenue Inspectorate of Rio de Janeiro for release of the imported goods 10.2 cm
12.2 cm COMMENTS	COMMENTS

Ministry of Health

National Secretariat of Health Control

ORDER NO. 20 OF 6 SEPTEMBER 1977

The Official in Charge of the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products of the National Secretariat of Health Control of the Ministry of Health, in exercise of the powers vested in him under article 45 (III) of Ministerial Order No. 2-RJ of 23 March 1977 and pursuant to article 6 and the opening provision and sole paragraph of article 36 of Act No. 6,368 of 21 October 1976 2/ and article 17 of Decree No. 78,992 of 21 December 1976, 3/ hereby issues the following instructions on the prohibition, restriction and control of the production, trading and use of substances which cause physical or psychic dependence and medicines containing such substances.

CHAPTER I

Substances whose use is prohibited for medical purposes

1. The use for medical purposes of the substances listed in schedule I hereto and of medicines containing them is expressly prohibited throughout Brazilian territory, together with their manufacture, import, export, re-export and marketing.

2. Only public organs and bodies specially authorized by the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) may carry out scientific research with the substances listed in schedule I or with medicines containing them.

2.1 Application for authorization for such research shall be made by the head of the public organ or body concerned, in compliance with the following requirements:

(a) A full research programme, signed by the head of the organ or body and the research workers;

(b) A list of the technicians who will take part in the research, accompanied by particulars showing their qualifications for the task;

(c) An undertaking signed by the head of the organ or body with regard to the supervision, control and recording of the substances or medicines used in the research;

(d) The submission to DIMED of quarterly reports on the progress of the research and, when it is concluded, a final report containing the findings.

3. The head of the public organ or body in which the research is carried out shall be responsible for the control, supervision and recording of the substances and medicines authorized to be used in the research, subject to the relevant instructions and other provisions at present in force or to be issued later. He shall also provide any information he is requested to furnish by the competent supervisory health authority.

3.1 The substances and medicines referred to in this section may not be handled except by the research worker responsible and on the research premises specified in the programme.

4. The import of substances or medicines for the purposes specified in section 2 shall be subject to the granting by DIMED of an import authorization and certificate.

4.1 The application for the import authorization and certificate shall be signed by the head of the public organ or body concerned and shall contain the following:

(a) A copy of the research programme approved by DIMED;

(b) The common name of the substance and synonyms for it;

(c) The name of the medicine containing it, where applicable;

(d) The classification of the substance;

(e) Its place of origin;

(f) The quantity provided for in the programme;

(g) The name and address of the public organ or body and research premises;

(h) The name and address of the enterprise importing the substance into Brazil, where applicable;

(i) The name and address of the exporting enterprise.

5. If the application is granted, 7 (seven) copies of a non-transferable import certificate shall be issued, for the following recipients:

First copy: National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED);

Second copy: importer;

Third copy: exporter;

Fourth copy: competent authority of the exporting country;

Fifth copy: Narcotic Drugs Suppression Service of the Federal Police Department in Rio de Janeiro;

Sixth copy: National Commission for the Control of Narcotic Drugs (CONFEN);

Seventh copy: the competent health authority of the State, Federal District or Territory.

6. The import certificate shall be valid only for the year for which it is granted.

7. Seven copies of the import certificate shall be issued with the import authorization, for the same recipients as listed in section 5 (five) of the present Order.

8. The substances listed in schedule I to the present order and medicines containing them may not enter Brazilian territory except through the competent Federal Revenue Inspectorate of the State of Rio de Janeiro and on production for each consignment of 4 (four) copies of a clearance permit for narcotic drugs or medicines or substances which cause physical or psychic dependence, conforming to specimen No. 10 annexed to Order no. 19/77. 5/

8.1 For this purpose, the person concerned shall submit to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) a commercial invoice for each consignment, giving full details of the name, nature, place of origin and quantity of the goods in question and the year and quarter to which the import authorization relates, to enable the clearance permit to be validated for removal of the goods from the Federal Revenue Inspectorate.

CHAPTER II

Substances and medicines capable of causing physical or psychic dependence and treated as equivalent to narcotic drugs for control purposes

PRESCRIPTION

9. Prescriptions containing a medicine in schedule III to the present Order capable of causing physical or psychic dependence may not be dispensed by pharmacies or chemist's shops unless:

(a) They are made out by a legally qualified practitioner;

(b) They are written on an official prescription form conforming to specimen No. 1 annexed to Order No. 19/77;

(c) They are written out in full legibly in Portuguese in ink and in the practitioner's own handwriting;

(d) They give the full name and address of the patient and bear the autograph signature of the practitioner, his name in full in legible script, the address of his residence or consulting rooms, his registration number in his professional association and the date of the prescription;

(e) They give the name of the medicine and the dose in legible writing;

(f) The amounts prescribed are given in Arabic numerals and in full;

(g) In the case of an animal, the prescription states the race, species, weight and other characteristics, the place where the animal is kept and the name and address of its owner, in addition to meeting the other requirements specified in this section;

(h) A reason is given for the use of the medicine concerned.

5/ Note by the Secretariat: E/NL.1978/9

9.1 A block of official prescription forms shall be provided free of charge directly by the competent health authority of the State, Federal District or Territory concerned, against a receipt, to legally qualified practitioners upon application in person or in writing, after completion of the appropriate form with autograph signatures attested by a notary.

10. In cases of extreme urgency and in the absence of the form referred to in section 9 (b), the prescription may be written on other paper, provided that, in addition to the details required by law for an official prescription form, it gives the reason for the use of the medicine and the time and place of the occurrence and bears the words "WARNING - MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE". The establishment which dispenses the prescription shall ask for and record the identity of the bearer of the prescription and submit the prescription to the competent health authority within 24 (twenty-four) hours.

11. In public, private or charitable medical or veterinary hospital or para-hospital establishments, medicines listed in schedule III to the present Order may be supplied to patients on prescriptions which are written on headed pale yellow hospital prescription forms of the establishment conforming to specimen No. 2 annexed to Order No. 19/77 and are signed by a practitioner who is on the active staff of the establishment or can show that he is the physician or veterinarian attending the patient or animal concerned.

11.1 Such prescriptions shall give the reason for employing the medicine, the full name of the patient in legible writing, the name of the hospital or para-hospital establishment and the number of the ward, room or bed occupied by the patient, in addition to meeting the requirements laid down in subsections (a), (c), (e), (f) and (g) of section 9 of the present Order, and may not be dispensed outside the establishment itself.

11.2 The prescriptions referred to in this article may be dispensed without the prior or subsequent approval of the competent health organ, which approval shall be replaced by that of the competent health authority on its visits of inspection.

11.3 In the medical dispensary of establishments using medicines listed in schedule III to the present Order, there shall be employed and made responsible a legally qualified pharmacist or other practitioner. In the absence of such a person, the physician or veterinarian officially responsible for the establishment shall be the custodian and person responsible for the supervision and control of the use of such medicines.

12. In public, private or charitable medical or veterinary hospital or para-hospital establishments, whether or not these establishments have their own dispensary, the senior physician or veterinarian on duty may, on application to the director by the head physician or veterinarian, have three of the medicines listed in schedule III to the present Order in his keeping for emergency cases.

12.1 In order to keep a check on the quantities supplied, the quantity originally applied for shall be replenished on presentation of the appropriate prescription on a hospital prescription form, subject to compliance with the other requirements laid down in the present Order.

13. Only one type of medicine listed in schedule III may appear on each prescription and only in the following quantities:

(a) For injections, up to 5 (five) ampoules;

(b) For oral use:

b.1 In solid form, 20 (twenty) tablets, dragées, capsules or pills, and 1 (one) pack in the case of products in the form of powder or granulates;

b.2 In liquid form, 1 (one) pack approved by the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED).

13.1 When a quantity greater than those specified in this section is prescribed, the prior approval of the authority shall be required and shall be shown on the prescription concerned.

14. Prescriptions for medicines listed in schedule III to the present Order shall be valid for 30 (thirty) days from the date of the prescription.

15. The substances listed in schedule II to the present Order may not be the subject of magistral prescriptions.

16. Public or private research and teaching establishments may make use of substances and medicines listed in schedules II and III to the present Order provided that the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) has specifically authorized such use and that the requirements laid down in sections 2.1, 3 and 3.1 of the present Order are complied with.

17. Research and teaching establishments already possessing the substances or medicines listed in schedules II and III to the present Order shall notify the fact to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) and to the competent health authority of the State or Territory concerned or of the Federal District, and shall state the amounts they have in stock.

RECORDS

18. All operations relating to the substances listed in schedules II and III to the present Order shall be recorded in a register conforming to specimen No. 3 annexed to Order No. 19/77, on the day of the operation itself and by the person in charge of the establishment concerned.

18.1 The competent health authority shall mark the register to record its opening and closing and shall initial each page.

18.2 Each page of the register shall be used to record one substance or medicine only.

18.3 All operations relating to the substances and medicines concerned shall be recorded meticulously, legibly and without alterations (amendments, erasures, blemishes or interlineations).

18.4 Corrections shall be made in the section headed "Comments".

19. Establishments which dispense prescriptions containing medicines listed in schedule III to the present Order shall, immediately after dispensing them, copy the prescription into the prescription book and record it in the register.

19.1 After being recorded, prescriptions and justifications for their use, where applicable, shall be filed in chronological order in the establishment concerned for inspection and approval by the competent health authority.

19.2 After approval, prescriptions and justifications for their use shall be kept on file in the establishment concerned for 5 (five) years, after which they may be destroyed.

20. Issues of the substances or medicines listed in schedules II and III to the present Order, if in the form of sales, shall be recorded by giving the following details: in the "PARTICULARS" column, the name and address of the buying enterprise and the form in which the substance or medicine was sold; in the column which follows the "STOCK" column, the name of the person responsible in the buying establishment; in the remaining columns, the details required for dispensing the prescription.

21. Issues of the substances concerned for use in the manufacture of preparations in the establishment itself shall be recorded by giving the following details: in the "PARTICULARS" column, the name and quantity of the preparations to be manufactured, and in the "COMMENTS" column the liquid volume of the batch (after sterilizing, filtering, bottling, etc.). The remaining columns shall be completed in the same way as for other issues.

22. Each entry in the register shall be matched in the files of the establishment by a voucher duly authenticated by the competent health authority: in the case of receipts, the clearance permit for narcotic drugs or substances causing physical or psychic dependence or the order form; in the case of issues, the order form or the medical prescription. Issues of substances for the manufacture of preparations shall be balanced by entries showing the receipt into stock of the batch concerned.

23. The vouchers in question shall be kept on file separately: receipt vouchers in date order, prescriptions in the order of their entry number in the prescription book and sales vouchers in alphabetical order of the buyer's name and in date order for each buyer.

23.1 The following documents shall vouch for the legality of entries recording the various operations connected with the substances and medicines to which the present Order refers: order forms, return notes, clearance permits for narcotic drugs or substances causing physical or psychic dependence, fiscal vouchers, registers, import vouchers, monthly sales statements and quarterly or annual balance sheets.

24. In hospitals and para-hospital establishments and in medical and veterinary services which do not have their own dispensaries, prescriptions for medicines in schedule III to the present Order shall be recorded as indicated in the opening provision and subsections of section 19, with the exception that only the name and place of stay of in-patients and the addresses of day patients and out-patients shall be entered in the "PARTICULARS" column.

25. In research and teaching establishments, requests for substances or medicines listed in schedules II and III shall be recorded immediately after supply to the research worker concerned, the purpose and reason being entered under "PARTICULARS" and the name of the person requesting the substance or medicine in the column following the "STOCK" column.

TRADE

26. Purchases of substances listed in schedule II to this Order and of medicines listed in schedule III thereto by pharmaceutical, hospital, para-hospital, research and teaching establishments shall not be made except by means of order forms validated by the competent health authority and in compliance with the following requirements:

(a) Orders shall be written legibly in Portuguese without erasures or alterations on printed forms conforming to specimen No. 4 annexed to Order No. 19/77 and shall state the designation, name and address and name of the person responsible, as regards the buying establishment, the designation, name and business address of the selling establishment, the precise description of the substances and medicines involved and their packaging and the quantities in Arabic numerals and in full;

(b) Lines on the order form which are not filled in shall be ruled through;

(c) Orders shall be in sextuplicate where both the buying and selling establishments are in the same State, in the Federal District or in the same Territory and in octuplicate where they are in different units of the Federation.

26.1 Approvals shall be valid for a period of 60 (sixty) days from the date on which they are given by the competent local health authority, and shall expire at the end of that period.

27. Orders shall first be taken by the seller for approval and stamping to the competent local health authority responsible for supervising the buying establishment, and subsequently, if the buyer and seller are located in different units of the Federation, the orders shall be taken to the competent health authority for the place in which the seller is located.

27.1 Where both the buying and selling establishments are in the same State, in the Federal District or in the same Territory, the competent health authority shall retain two copies of the order form for control purposes and return the remaining copies to the seller duly validated, stamping one of them with the words "consignment note", to be handed to the buyer with the goods; one copy shall be retained by the seller, who shall file it as a sale voucher, and the remaining two copies shall be forwarded by the seller to the Narcotic Drugs Suppression Service of the Federal Police Department.

27.2 Where the buying and selling establishments are not both in the same State, in the Federal District or in the same territory, in addition to the requirements of the preceding subsection being met, the seller shall forward the two additional copies of the form respectively to the competent health authority and to the Narcotic Drugs Suppression Service of the Federal Police Department for the unit of the Federation in which the establishment is situated.

28. Supervisory health authorities shall not, without the express authorization of the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED), approve orders which would bring stocks up to amounts greater than the requirements for six (6) months.

28.1 To obtain the concession mentioned in this section, the person concerned shall, in the "Comments" section or on the back of the order form, state the remaining stocks and the average monthly consumption over the previous 12 (twelve) months.

29. Only the competent health authorities may alter or amend orders, and in such a case they shall validate the change clearly on the form and report the matter, together with the reasons for the change, to the competent health authority which earlier approved the order.

30. Substances or medicines listed in schedules II and III to this Order shall be returned by the buyer to the seller in the following manner:

(a) The buyer shall submit to the competent local health authority a statement giving his reasons for wishing to return the goods concerned, accompanied by 6 (six) or 8 (eight) copies, as the case may be, of a printed return note conforming to specimen No. 4 annexed to Order No. 19/77, but with the words "ORDER FORM" replaced by the words "RETURN NOTE";

(b) If the reasons are accepted, the return shall take place in the same manner as the purchase and in accordance with the provisions of sections 26 (a), (b) and (c), 27, 27.1 and 27.2 of the present Order;

(c) The seller shall inform the competent local health authority when he receives the returned goods.

31. Sales shall not take place except on presentation of order forms validated by the competent health authority and the entire order concerned shall be delivered at one and the same time.

32. Failure to comply with the requirements set out in the opening provision and subsections of section 26 and in sections 27, 27.1, 29 and 31 shall entail suspension of approval for orders in which the offending establishment appears as buyer or seller.

33. In the event of the register or any substances and/or medicines listed in schedules II and III to the present Order being impounded on the premises of any pharmaceutical, hospital, para-hospital, research or teaching establishment by order of the Government or the courts, the establishment concerned shall be barred from using the said substances and/or medicines until a new register, authenticated by the competent health authority, has replaced the impounded register.

34. The import, export and re-export of the substances and medicines listed in schedules II and III shall be subject to authorization by the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED).

35. For the purposes of the preceding section, the person concerned, duly authorized to deal with the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED), shall apply for an import, export or re-export certificate and authorization as provided in sections 5, 6, 7, 8 and 8.1 of the present Order.

36. The requirements laid down in the present Order shall apply to importers where appropriate.

MONTHLY SALES STATEMENTS

37. The persons in charge of enterprises and establishments conducting any activity whatsoever contributing towards the production and/or marketing of the substances and medicines listed in schedules II and III to the present Order shall, before the tenth working day of each month, forward to the competent local health authority a statement of the sales made during the preceding month to other enterprises or establishments or hospital, para-hospital, research or teaching bodies.

37.1 The statements shall be prepared as follows on printed forms conforming to specimen No. 5 annexed to Order No. 19/77: the substances and medicines concerned shall be listed in the order in which they appear in schedules II and III; the amounts shall be given in Arabic numerals and in full and the form in which the substances or medicines were supplied shall be indicated; the dates of despatch and of approval by the local health department, the names of the buying enterprises or establishments or hospital, para-hospital, research or teaching bodies and the names and addresses of the persons respectively responsible for them at law shall be shown.

38. The persons in charge of enterprises or establishments conducting any and every activity contributing towards the production and/or marketing of the substances and medicines listed in schedules II and III to the present Order shall, before the tenth working day of the months of January, April, July and October, forward to the competent local authority two copies of a quarterly balance sheet prepared on printed forms conforming to specimens Nos. 6 or 7 annexed to Order No. 19/77 and showing the amounts acquired, sold, used and held in stock; one copy, duly authenticated, shall be returned to the person concerned as proof of delivery.

39. For the quarterly balance sheets, the specimens mentioned in the preceding section shall be used by dispensing and industrial establishments and by chemists' shops, distributors, exporters and agents respectively.

ANNUAL BALANCE SHEETS

40. Pharmaceutical establishments of every kind shall, before the 10th (tenth) day of January each year, forward to the competent local health authority two copies of an annual balance sheet conforming to the specimens prescribed in section 39 and to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) one copy thereof.

40.1 The provisions of this section shall apply to public, private and charitable medical and veterinary hospital and para-hospital establishments and to research and teaching establishments.

41. Persons in charge of public, private and charitable medical and veterinary hospital and para-hospital establishments and of research and teaching establishments shall, wherever there is any consumption of the substances and medicines listed in schedules II and III, forward to the competent local health authority before the 10th (tenth) day of each month two copies of a monthly statement of use conforming to specimen No. 8 annexed to Order No. 19/77. One copy shall be authenticated and then returned to the person concerned as proof of delivery. Research and teaching establishments shall use specimen No. 9 annexed to Order No. 19/77.

42. Failure to submit the required statements and balance sheets within the specified period or their submission with erasures, alterations or errors shall result in suspension of approval for orders for substances and medicines listed in schedules II and III in which the offending establishment appears as buyer or seller.

AUTHORIZATION

43. Any enterprise that extracts, produces, manufactures, processes, prepares, possesses, imports, exports, re-exports, dispatches, transports, displays, offers, sells, buys, exchanges, transfers or acquires for any purpose a substance listed in schedule II to this Order or a raw material intended for the preparation of such a substance shall obtain a special authorization from the National Division of

Health Control for Drugs, Medicines, Pharmaceutical Materials, Dietetic and Related Products (DIMED), and comply with the other requirements of the law, before embarking on any of the above operations.

44. On the cessation of any of the operations enumerated in the previous section, the persons responsible for the enterprises concerned shall make an inventory of their remaining stocks within 30 (thirty) days and surrender them to the competent health authority for suitable disposal.

PACKAGING

45. Packaging for the substances and medicines listed in schedules II and III to this Order shall be such that it cannot be tampered with and that the substances or medicines concerned are easily identifiable.

46. The labels and packagings of medicines containing substances capable of causing physical or psychic dependence shall have a horizontal black band encircling the middle third of the entire package, equal in width to not less than one third of the length of the longer side of the main face, and bearing the words "To be sold on medical prescription" and "Warning - may cause physical or psychic dependence".

46.1 Instructions for use of the medicines referred to in this section shall carry clearly and in lettering larger than the text the words "WARNING - MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE".

47. The medicines listed in schedule III to the present Order shall be labelled and packaged as follows:

(a) Injectable preparations shall have their name printed on the bottle and be put up in boxes containing 5 (five), 10 (ten) or 15 (fifteen) ampoules or in 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 para-hospital organizations;

(b) Medicines in solid form (tablets, dragées, capsules, pills and suppositories) shall be put up in distinctive packaging in amounts of 5 (five) and 20 (twenty) dosage units for sale to the public and of 50 (fifty), 100 (one hundred) and 200 (two hundred) dosage units when intended for use by hospital and para-hospital organizations;

(c) Medicines 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 para-hospital organizations;

(d) Medicines 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 Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) shall be responsible for deciding the quantity which each package of a topical remedy shall contain.

48. The sale of substances or medicines listed in schedules II and III to the present Order in any of the packagings mentioned in the various subsections of the proceeding section shall not be permitted if the printed material does not comply with the requirements of sections 45, 46 and 46.1.

49. The labels, instructions for use and packagings of the medicines listed in schedule III to the present Order shall, where the medicines are intended for use by hospital and para-hospital establishments, including veterinary establishments, bear in clearly legible characters the words "FOR SALE EXCLUSIVELY TO HOSPITAL OR PARA-HOSPITAL ORGANIZATIONS".

50. An enterprise which is the registered owner of a medicine containing in its formula a substance listed in schedule II shall have 60 (sixty) days from the date of publication of the present Order in which to submit to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) designs of specimen labels showing their proposed size and giving instructions for use and packaging which comply with the provisions of the present Order.

51. The failure of medicines at present in establishments to comply with the provisions of sections 45, 46, 46.1, 47 (a), (b), (c), (d) and (e) and 48 shall not constitute a health offence if the medicines were acquired before the date of publication of the present Order.

CHAPTER III

Substances and medicines capable of causing physical or psychic dependence listed in schedules IV and V

PRESCRIPTION

52. The sale to the public of substances or medicines listed in schedules IV and V to the present Order shall be confined to pharmacies and chemists' shops and may not take place except on presentation of a prescription written on a practitioner's prescription form, and in compliance with the requirements laid down in subsections (a), (c), (d), (e), (f) and (g) of section 9 (nine).

53. For the purposes of the previous section, the term "practitioner's prescription form" means a sheet of light blue paper from a block of forms printed in accordance with the specimen annexed to the present Order, in two parts, intended respectively for the physician and for the establishment which dispenses the prescription.

53.1 The practitioner himself shall be responsible for having the blocks of forms referred to in this article printed and numbered.

53.2 Practitioner's prescription forms shall be numbered consecutively, starting with form No. 1 in the practitioner's first block of forms.

54. In public, private or charitable medical or veterinary hospital or para-hospital establishments, the prescribing for in-patients or out-patients of substances or medicines listed in schedules IV and V shall not take place except on headed pink hospital prescription forms of the establishment conforming to the specimen appearing in the present Order which are signed by a legally qualified practitioner who is on the active staff of the establishment or can show proof that he is the physician or veterinarian attending the in-patient, day patient or out-patient, whether a person or an animal, concerned.

54.1 In each hospital or para-hospital establishment, the hospital prescription forms shall be numbered consecutively, starting with form No. 1 in the first block of forms.

54.2 The establishment concerned shall be responsible for having the blocks of forms referred to in this article printed and numbered.

54.3 Prescriptions on hospital prescription forms dispensed by the establishment itself shall be filed in chronological order and remain at the disposal of the competent health authority for due inspection.

55. The provisions of sections 11.3, 12.1, 13, 13.1 and 14 of the present Order shall apply to substances and/or medicines listed in schedules IV and V.

56. In public and private research and teaching establishments, the use of the substances and medicines listed in schedules IV and V shall be governed by the provisions of section 16 of the present Order.

RECORDS

57. Prescriptions for substances and/or medicines listed in schedules IV and V to the present Order shall be recorded in the following manner:

(a) They shall be numbered and entered in the prescription book and then initialled by the technician in charge;

(b) Daily records shall be kept of dispensed prescriptions, by substance and/or medicine, stating the serial number of the prescription concerned and the total quantity of units supplied;

(c) For the purposes of the records referred to under subsection (b), use shall be made of a register conforming to specimen No. 3 annexed to Order No. 19/77 or such other form of record as is authenticated by the competent health authority;

(d) The records shall comply with the requirements set out in the opening provision and subsections of section 18.

58. Only the provisions of subsections (b), (c) and (d) of the preceding section shall apply to those hospital establishments which do not have their own dispensaries with a pharmacist in charge.

59. The provisions of sections 18, 18.1, 18.2, 18.3 and 18.4 shall apply to enterprises that extract, produce, manufacture, process, prepare, possess, import, export, re-export, despatch, transport, display, offer, resell, transfer or acquire for any purpose substances or medicines listed in schedules IV and V to the present Order.

TRADE

60. The provisions of sections 8, 8.1, 26 (a), (b) and (c), 26.1, 27, 27.1, 27.2, 28, 29, 30 (a), (b) and (c), 31, 32, 33, 34, 35 and 36 of the present Order shall apply to the purchase, sale and return of substances and/or medicines listed in schedules IV and V.

61. The provisions of sections 43 and 44 shall apply to any industrial pharmaceutical enterprise, warehouse or distributor which extracts, produces, manufactures, processes, prepares, possesses, imports, exports, re-exports, despatches, transports, displays, offers, resells, exchanges, transfers or acquires a substance listed in schedule IV or a raw material intended for the preparation of such a substance.

PACKAGING

62. The packaging and labelling of substances and medicines listed in schedules IV or V shall comply with the provisions of sections 45, 46, 46.1, 47 (a), (b), (c), (d) and (e), 48, 49, 50 and 51.

GENERAL PROVISIONS

63. Magistral prescriptions for and preparations of medicines containing phenobarbitol (5-ethyl-phenylbarbituric acid) in schedule IV to the present Order shall be excluded from the provisions of sections 52, 53, 54, 55, 56 and 58.

64. Medicines containing the substances clobenzorex, diethylpropion, fenfluramine, fenproporex and mefenorex in schedule II have been listed in schedule V and are subject to the provisions of chapter III of the present Order.

65. The substances and medicines listed in schedules II, III, IV and V to the present Order shall be kept under strict supervision and remain in the custody of the person in charge of the establishment.

66. Samples of substances capable of causing physical or psychic dependence and of medicines containing such substances may not be distributed to physicians, dentists, veterinarians and pharmacists or otherwise.

67. Enterprises which hold licences for or are the registered owners of medicines that are not listed in schedules III and V but contain substances listed in schedules II and IV shall within 30 (thirty) days inform the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) of the name of the medicine, the number of the licence or registration and the date of its issue.

68. Any substances and medicines listed in schedules II, III, IV and V which are seized in connexion with the infringement of any provision of the present Order shall be handed over by the seizing authority to the competent health authority of the State, Federal District or Territory where the seizure took place, and a detailed report on the occurrence shall be made to the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED).

69. Advertisements for substances capable of causing physical or psychic dependence and for medicines containing such substances may not appear except in technical and scientific journals or publications the circulation of which is confined to physicians, dentists, veterinarians and pharmacists.

70. In the event of the bankruptcy or judicial liquidation of any establishment referred to in the present Order, the competent health authority shall arrange for the receipt on deposit of any stocks taken into safe keeping or forming part of the liquidation assets, on notice from the court dealing with the proceedings.

71. No sale by judicial auction of substances and/or medicines listed in schedules II, III, IV and V shall take place without the presence of representatives of the National Division of Health Control for Drugs, Medicines, Pharmaceutical Materials and Dietetic and Related Products (DIMED) or a related health organ empowered by the Service, and bidding shall be confined to natural or juridical persons duly authorized by the competent health authority.

72. The competent health authorities of the Army, Navy and Air Force shall, in addition to complying with those provisions of the present Order which are applicable to the health services within their competence, forward annually to the competent health authority general balance sheets showing receipts, consumption and stocks of the substances and/or medicines listed in schedules II, III, IV and V, in conformity with the requirements of the present Order.

73. The competent health and police authorities shall assist each other in any steps required to ensure strict compliance with the provisions of the present Order and shall observe secrecy in their investigations.

74. Failure to comply with the requirements of the present Order shall be a health offence rendering the offender liable to prosecution and punishment under Act No. 6,437 of 20 August 1977, without prejudice to any other penalty, civil or criminal, to which he may be liable.

75. 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.

76. The present Order shall come into force on the day of its publication.

77. Orders Nos. 18 of 28 September 1973 and 16 of 31 May 1976 of the former National Medical and Pharmaceutical Control Service are hereby repealed together with any other conflicting provisions.

Fernando Ayres da Cunha

SCHEDULE I

PROHIBITED SUBSTANCES

	INTERNATIONAL NON-PROPRIETARY NAME	OTHER NON-PROPRIETARY OR TRIVIAL NAMES	CHEMICAL NAME
1.	Adrenolutin	-	N-methyl-5,6-dihydroxyindoxyl
2.	Banisterine	-	7-methoxy-1-methyl-9H-pyrido[3,4-b]-indole
3.	Bufotenine	-	5-hydroxy-N-dimethyltryptamine
4.	-	DET	N,N-diethyltryptamine
5.	-	DMHP	3-(1,2-dimethylheptyl)-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran
6.	-	DMT	N,N-dimethyltryptamine
7.	(+)-Lysergide	LSD, LSD-25	
8.	-	mescaline	3,4,5-trimethoxyphenethylamine
9.	-	parahexyl	3-hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran
10.	-	psilocine, psilotsin	3-(2-dimethylaminoethyl)-4-hydroxyindole
11.	Psilocybine	-	
12.	-	STP, DOM	2-animo-1-(2,5-dimethoxy-4-methyl) phenylpropane
13.	-	tetrahydrocannabinols, all isomers	1-hydroxy-3-pentyl-6a,7,10,10a-tetrahydro-6,6,9-trimethyl-6-H-dibenzo[b,d]pyran

SCHEDULE II

SUBSTANCES TREATED AS EQUIVALENT TO NARCOTIC DRUGS WITH RESPECT TO CONTROL OF SALE AND USE

	SUBSTANCE	CHEMICAL NAME
1.	Amphetamine	(±)-2-amino-1-phenylpropane
2.	-	amphetamine (4-chlorphenoxy)acetate
3.	-	amphetamine phosphate
4.	-	d-amphetamine sulphate
5.	-	dl-amphetamine sulphate
6.		hydroxyamphetamine hydrobromide

	SUBSTANCE	CHEMICAL NAME
7.	-	benzyl carbinamine sulphate
8.	Chlorphentermine	
9.	Clobenzorex	
10.	Dexamphetamine	
11.	Diethylpropion	2-(diethylamino)-1-phenyl-1-propanone
12.	Fenfluramine	
13.	Fenproporex	
14.	Mefenorex	
15.	Methamphetamine	(+)-2-methylamino-1-phenylpropane
16.	-	d-desoxyephedrine hydrochloride
17.	-	methylamphetamine hydrochloride
18.	-	dl-phenyl-2-methylaminopropane hydrochloride
19.	Methaqualone	
20.	Methylphenidate	2-phenyl-2-(2-piperidyl)acetic acid, methyl ester
21.	-	2-phenyl-2-(2-piperidyl)acetic acid, methyl ester hydrochloride
22.	Phencyclidine	
23.	Phenmetrazine	3-methyl-2-phenylmorpholine
24.	-	2-phenyl-3-methyltetrahydro-1,4-oxazine hydrochloride
25.	Phentermine	
26.	R 382	phenyl-methylmorpholine-(dimethylchloro)xanthinate
27.	Tanphetamin	d-amphetamine tannate

SCHEDULE III

MEDICINES TREATED AS EQUIVALENT TO NARCOTIC DRUGS WITH RESPECT TO CONTROL OF SALE AND USE

ADJUVEX	DEXAMIL SPANSULE	METAGEN	PRELUDIN
AMBAR	DEXEDRINE SPANSULE	METARELAX	PRELUDIN COMPOUND
ANOREXIL	DEXEDRINE SULPHATE	METHEDRINE	PSYCHERGINE
BENZEDRINE	DIRAM	METOLIL	REDUIEX
BENZEDRINE SULPHATE	EUPHASED	METOLIL A	REMOÇAN
CAFILON	HISTIMULINA (ORAL SOLUTION)	METOLIL S	RENOVAL
CALMINE	HYPNOLON	METOLIL T	RITALIN
CALMOGEN	LINIX	NIRVALENE	SACYETIL
CALUDE	LIPAX	OBESITRAT	SONOPAX
CORIGRIPE	LUCOFEN A.P.	OBSOSTOP	SYNA-BOND
DAPRISAL	MANDRIX	ORTENAL	TRANQUILASE
DESBUTAL	MEQUALON	PHELONTIN	

SCHEDULE IV

SUBSTANCES IN RESPECT OF WHICH PUBLIC SALE IS CONTROLLED THROUGH PRESCRIPTION

SUBSTANCE

1. Allobarbital or allobarbitone
2. Amobarbital and its sodium salt
3. Aprobarbital and its sodium salt
4. Barbital and its sodium salt
5. Butabarbital and its sodium salt
6. Butalbital
7. Butallylonal
8. Butethal
9. Butylvinal
10. Cyclobarbital
11. Glutethimide
12. Heptabarb
13. Hexethal and its sodium salt
14. Hexobarbital and its sodium salt
15. Itobarbital
16. Meprobamate
17. Metharbital
18. Methitural and its sodium salt
19. Methohexital and its sodium salt
20. Pentazocine
21. Pentazocine butylaminosulphonate
22. Pentobarbital and its sodium salt
23. Phenobarbital
24. Probarbital and its calcium and sodium salts
25. Prominal
26. Propallylonal
27. Secobarbital and its sodium salt
28. Talbutal
29. Thiamylal and its sodium salt
30. Thiopental and its sodium salt
31. Vinbarbital and its sodium salt

SCHEDULE V

MEDICINES IN RESPECT OF WHICH SALE AND USE ARE CONTROLLED THROUGH PRESCRIPTION

ABISTIL

ABULEMIN

ABULEMIN AP 6/

ADIPENAN

AFLITIL

ALBATON

AMFEPRAMONE (see diethylpropion)

ANDREGEN

ANDRIOSEDIL

ANOBESINA

ANOGRAX

APEX

BENASON

BIOTRIL

BRIETAL SODIUM

BUTIAL

"BUTIBEL"

BUTILSED

BUTISOL SODIUM AND BELLADONNA

BYROFEN

CALMINE

CALMOGEN

CALUDE

CANEUM

CLOBENZOREX - any pharmaceutical form or manufacturer

CORPOBEL

CORPOREX

CYCLOBARBITAL (SANTA CATARINA)

DELGAR

DEPROMAT

DESOBESI "M"

DESOBESI "O"

DIANOREX

DIATREX

DIATREX AP

DIETACAPS

DIETEX

DIETHYLPROPION - any pharmaceutical form or manufacturer

DIMAGRIN

DIMINTEL

DINAMAGRA AP

DOBESIX LP

DORFIN

DORIDEN

ELEGANCAPS

ELEGANTIN

ELEPSIN

ELESBEL

ELMONAL

ELMONAL GEL

EMAGRECIL

EMAGRETEX

EMAGRIL

EMAGRIN

EQUANIL

ESBELTINA

ESBELTRAT

EUFORIL

FASTICAPS

FASTINAN

FASTINAN AP

FATINIL

FATINIL AP

FEDEPAX

6/ Note by the Secretariat: Translator believes AP could mean ação prolongada, i.e. long-lasting effect.

FEMERON

FENFLURAMINE - any pharmaceutical form or manufacturer

FENIDEX

FENIDEX AP

FENO-MINAL

FENOREX

FENOREX AP

FENPROPOREX - any pharmaceutical form or manufacturer

FENPROXIN

FIDECAPS

FLOBESIN

FRENAFON

GULASTOP

GULOCAPS

HARTOL

HASTIL

HIPOFAGIN

HORMINAL

HYPNOLON

INIBEX

INOBESIN

INOBESIN AP

ISOAMITIL

ITRIDAL

KIDORN

LEPENIL

LINOPEN

LINOPEN AP

LIPENAN

LIPENAN AP

LIPESE

LIPEX

LIPIDIN

LIPIONEX

LIPOCLASE

LIPOCLASE AP

LIPOEX

LIPOFLEX

LIPOGEN

LIPOGRASSIL

LIPOL

LIPOLIN

LIPOLIN AP

LIPOLISENE AP

LIPOLISENE

LIPOMAX

LIPOMAX AP

LIPOREX

LIPOREXIN

LIPORINE AP

LIPOSTIL

LIPOSTIL AP

LIPOVITA

LIPOVITA AP

LIPOSID

LISALIPOL

LUTAWIN

MAGRENE

MAGRESSE

MALIN

MAPROBAL

MEDICOL

MEFENOREX - any pharmaceutical form or manufacturer

MEPROBAMATE - any pharmaceutical form or manufacturer

MEPROFENIL

MEPROLEN

MEPROMAX

MEPRONEURAN

MEPRONEURAN WITH PHENOBARBITAL

MEPROSAY

MEPROSEDAN

MEPROSIN

MEPROSIN FOR CHILDREN

MESSAPIA

MILTOWN

MINIFAGE

MINIFAGE AP

MINOREX

MODELIN

MODERAFON

MODERAL

MODERAMIN

MODERAN AP

MODERAPE

MODERAPE AP

MODERASIN

MODEREX

MODERIL

MODERINE

MODEVYR

MUCONIL

NAMURON

NARCOBASOL

NARDIL

NEGATAN

NEGATAN AP

NEMBUTAL

NEMBUTAL SODIUM

NEURIPLEX

NEUROCONTROL

NEURO-CONTROLE

NEUROMINAL

NILIPOID AP

NOBESE

NOBESE AP

NOCTENAL

NOREXIL

NOREXON

NOREXON RETARD

OASIL

OBELEX

OBENIL

OBESAN

OBESICAPS

OBESICAPS THYROID

OBESICAPS THYROID AP

OBESIL

OBESILESS

OBESITOL

OBESONON

OBEX

OPTADORM

PASSEDAN

PENTOBARBITAL SODIUM

PERNEURIN

PESEX

PESEX AP

PESONEX

PONDEREX

PONDEREX AP

PONDERIL

PONDERON

PONDINOL

PONIL

PROBESE, SIMPLE

PROBESE, COMPOUND

PROLINAN

PROMADION

PROPIOFEN

PROPOREX

PROPOREX AP

PROTEUFORIL

PROZEPIN

REDUFOME

REDULIP

REDUX

REGIM

REGI-MEN

RELAXAN

REPESAN

REPRIMIL

REVONAL

SANINGER

SECONAL SODIUM

SEDOBASOL

SEDOMEPRIL

SEDOPLEX

SICOMATIL

SINTONAN

SOLAN

SOMBULEX

SOMNIFENE

SONOASIL

SONOPENIL

SOSSEGON

SUPREFON

SURITAL

SYMPLEXONAL

TEMIRAN

TEMIRAN DOSPAN

THIONEMBUTAL

THIOPENTAL - any pharmaceutical form or manufacturer

TRANQUILEX

TRANQUILEX FOR CHILDREN

TRANQUILIN

TRANQUISAN

VACOTONIL

XANASEDIN

BLOCK OF PRACTITIONER'S PRESCRIPTION FORMS

PRACTITIONER'S PRESCRIPTION FORM

Serial No. (printed) A
Dr.
Name of patient
Address
Date
Medicine

12 cm

PRACTITIONER'S PRESCRIPTION FORM

Serial No. (printed) B
WARNING - MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE
Dr.
Consulting rooms or residence
Practitioner's association
Name of patient
Address
Date

12 cm

Name and address of printer

Characteristics

light blue paper with two perforated sections
A - to be retained by physician or veterinarian
B - to be retained by pharmacy or chemist's shop

The physician may write any necessary comments on the back.
Part B is to be signed by the physician in his own handwriting.
Part B is to be kept on file by the dispensing establishment after it has filled the prescription.

BLOCK OF HOSPITAL PRESCRIPTION FORMS

HOSPITAL PRESCRIPTION FORM

Serial No. (printed) A
(Name of establishment and other particulars)
Director in charge
Address
Name of patient
Section bed
Ward
Out-patient department
Use
Medicine
(to be retained by hospital)
Signature
Practitioner's association

WARNING - MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE

HOSPITAL PRESCRIPTION FORM

Serial No. (printed) B
(Name of establishment and other particulars)
Director in charge
Address
Name of patient
Section bed
Ward
Out-patient department
Medicine
Signature
Practitioner's association
(to be retained by pharmacy or chemist's shop)

WARNING - MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE

12 cm

Characteristics

Substances and medicines listed in schedules IV and V to Order No. 20/77
pink paper
Two perforated sections
A - to be retained by hospital
B - to be retained by pharmacy or chemist's shop where appropriate.

The practitioner may write any necessary comments on the back of the form.
The form is to be signed by the practitioner in his own handwriting.
Part B is to be kept on file by the dispensing establishment after it has filled the prescription.