



# LAWS AND REGULATIONS

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

*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.*

CHILE

Communicated by the Government of Chile

### NOTE BY THE SECRETARIAT

- (a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.
- (b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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Republic of Chile  
Ministry of Health  
Chilean Institute of Public Health  
National Control Department

E/NL.1983/17

Ordinance No. 930. Change in drug sale regulations

Santiago, 28 April 1982

From: Director, Chilean Institute of Public Health

This is to inform you that, in compliance with the provisions of international treaties to which Chile is a party and in order to prevent the improper use of the below-mentioned product in Chile, the requirement that it is to be sold "under medical prescription" has been changed to read "under filed medical prescription", with effect from the 14th of this month.

<u>Manufacturer</u>	<u>Product</u>	<u>Active principle</u>
Laroche Navarron	FILINASMA	Amobarbital

The ruling specifies that pharmacies may sell their existing stocks as labelled, but subject to the new sales regulation of "under filed medical prescription".

Please take the necessary steps to ensure that pharmacies within your jurisdiction comply, from this date, with this ordinance by selling the above product "under filed medical prescription" only.

Yours sincerely,

(Signed) Joaquín Larrain Gana  
Colonel of the Army (Ret.)  
Director, Chilean Institute of  
Public Health

Republic of Chile  
Ministry of Health  
Chilean Institute of Public Health  
National Control Department

E/NL.1983/18

Ordinance No. 1023. Change in drug sale regulations

Santiago, 4 May 1982

From: Director, Chilean Institute of Public Health

This is to inform you that, in order to prevent non-compliance with the requirement that the following products are to be sold under medical prescription only, and also to prevent their improper use in Chile, there has been a change in

the regulations governing their sale, which now require that, with effect from 20 April of this year, they are to be sold "under filed medical prescription" only.

<u>Manufacturer</u>	<u>Product</u>	<u>Active principle</u>
Recalcine S.A.	P-92	Magnesium Pemoline
Silesia S.A.	DEADYN	Pemoline

The ruling specifies that pharmacies may sell their existing stocks as labelled, but subject to the new sales requirement for a "filed medical prescription".

Please take the necessary steps to ensure that pharmacies within your jurisdiction comply, from this date, with this ordinance by selling the above products under a "filed medical prescription" only.

Yours sincerely,

(Signed) Joaquín Larrain Gana  
Colonel of the Army (Ret.)  
Director, Chilean Institute of  
Public Health

Official Gazette [Diario Oficial] No. 31269  
20 May 1982

E/NL.1983/19

THE CHILEAN MINISTRY OF PUBLIC HEALTH ISSUES A WARNING  
AND RESTRICTS THE MARKETING OF SPECIFIED PRODUCTS

Santiago, 9 February 1982

The following Decree has been issued today.

No. 25. Bearing in mind the provisions of articles 1 to 3, 9, 90 and 91 of the Public Health Code, approved by Decree Law No. 725 of 1968,

Taking into account articles 1, 4 and 6 of Decree Law No. 2763 of 1979 and the powers vested in me under article 32, item 8, of the Political Constitution of the Republic of Chile, and further

Considering:

1. The growing problem of drug addiction among children, with its harmful effects on the health of individuals and on society in general,
2. That, depending on the dosage, exposure to organic chemical solvents and diluents can cause severe damage to the central nervous system and to other organs of the human body,
3. Police reports indicating that the most common form of drug addiction among children is the inhalation, for long periods and in enclosed areas, of adhesive products and glues containing organic chemical compounds as solvents,

I DECREE

1. All adhesive products and glues marketed in Chile and containing an organic chemical compound as a solvent or diluent shall bear a clearly and distinctly marked printed warning or label, in white letters against a black background or in black letters against a white background and enclosed in a rectangle covering not less than ten per cent of the container's surface area, with the following words in Spanish:

"PROLONGED INHALATION OF THIS PRODUCT WILL CAUSE IRREPARABLE BRAIN DAMAGE."  
MINISTRY OF HEALTH

2. The warning specified in the preceding paragraph shall be printed in sanserif characters and medium italic type of a size proportional to that of the rectangle referred to in paragraph 1.

3. The same wording shall be included in the advertising messages for these products that are carried in newspapers, magazines, television commercials, radio broadcasts, advertisements shown in cinemas and in any other public communication medium through which these products are offered for sale to the public. Following television commercials and cinema advertisements, a frame containing the warning described in paragraph 1 of this Decree and filling the entire area of the screen shall be projected for not less than five seconds.

4. It shall be prohibited to sell adhesives and glues containing the organic chemical solvents or diluents referred to in the preceding paragraphs to children under the age of 14 years.

5. Failure to comply with these provisions shall be punished as follows:

(a) Articles that have not been labelled as specified in paragraphs 1 and 2 of this Decree shall be seized, destroyed or otherwise rendered unusable;

(b) Offenders under paragraph 3 of this Decree shall be punished under the other applicable sanctions and procedures provided for in Book IX of the Public Health Code.

6. The provisions of this Decree shall not affect the implementation and force of Ruling No. 9 of 2 January 1975, issued by the Director of the National Health Service, which prohibits the use of benzol or benzene as diluents in adhesives, glues, paints and other substances mentioned therein.

7. The provisions of this Decree shall come into force six months after its publication in the issue of the Official Gazette dated 20 November 1982.

To be duly noted, recorded, published and entered in the Official List of Laws of the Office of the Comptroller-General of the Republic.

AUGUSTO PINOCHET UGARTE, General of the Army and President of the Republic.

Roberto Verdugo Gormaz, Deputy Minister of Economic Affairs, Development and Reconstruction

Rear Admiral Hernán Rivera Calderón, Minister of Health.

Forwarded for your information by Dr. Augusto Schuster Cortés, Assistant Under-Secretary for Health.

Republic of Chile  
 Ministry of Health  
 Chilean Institute of Public Health  
 National Control Department

E/NL.1983/20

Ordinance No. 1327. Change in Drug Sale Regulations

Santiago, 7 June 1982

From: Director, Chilean Institute of Public Health

This is to inform you that, in order to prevent non-compliance with the requirement that the following products are to be sold under medical prescription only, and also to prevent their improper use in Chile, there has been a change in the regulations governing their sale, which now require that, with effect from 1 June of this year, they are to be sold "under filed medical prescription" only.

<u>Manufacturer</u>	<u>Product</u>	<u>Active principle</u>
Andromaco S.A.	INOCOLME tablets	Phenproporex
Quinica Hoechst	SURALGON tablets	Phenproporex
Silesia S.A.	SINAPET capsules	Phenproporex
Saval S.A.	SALCAL tablets	Phenproporex
Recalcine S.A.	PLUMIVIN tablets	Phenproporex

The ruling specifies that pharmacies may sell their existing stocks as labelled, but subject to the new sales requirement for a "filed medical prescription".

Please take the necessary steps to ensure that pharmacies within your jurisdiction comply, from this date, with this ordinance by selling the above products under a "filed medical prescription" only, and carry out the appropriate inspections.

Yours sincerely,

(Signed) Dr. Hernán Lobos Domero  
 Deputy Director, Chilean Institute of  
 Public Health

Republic of Chile  
 Ministry of Health  
 Chilean Ministry of Public Health  
 National Control Department

E/NL.1983/21

THE MINISTRY OF THE INTERIOR APPOINTS A COMMITTEE TO STUDY THE PROBLEM  
 OF DRUG ADDICTION AND ALCOHOLISM AMONG YOUNG PEOPLE

Santiago, 13 July 1982

The following decree has been issued today.

No. 871. Bearing in mind the provisions of article 32, item 8, of the Political Constitution of the Republic, and

Considering that juvenile alcoholism and drug addiction have increased considerably in Chile and throughout the world, and that the Supreme Government cannot remain inactive in the face of these evils,

I DECREE

Article 1. A Committee shall be appointed to study the question of drug addiction and alcoholism among young people, the causes from which these evils stem and the problems to which they give rise, and shall propose measures designed to eliminate this phenomenon through actions to be implemented nationally under the authority of the Ministry of the Interior.

Article 2. This Committee shall act as an advisory body to the President of the Republic and shall be composed of the following persons: the First Lady of the Nation, who shall preside; the Under-Secretary of the Interior, who shall be the Vice-Chairman, replacing the Chairwoman in her absence; the Under-Secretaries of Health, Education and Justice; the legal advisor to the First Lady of the Nation; the Executive Vice-Chairwoman of the National Foundation for Community Aid; a representative of the University of Santiago; a representative of the Catholic University of Santiago; a representative of the Institute of Pedagogical Sciences; three members appointed by the President of the Republic, and five members of the professional community: one lawyer, one psychiatrist, one sociologist, one psychologist and one social worker, all to be appointed by the First Lady of the Nation.

Article 3. The Committee shall be entitled to call upon any public or private organizations for assistance in performing its task, and these organizations shall be required to provide such assistance.

To be duly noted, recorded, communicated and published.

AUGUSTO PINOCHET UGARTE, General of the Army and President of the Republic.

Enrique Montero Matx, Brigadier General of the Air Force, Minister of the Interior.

Forwarded for your information by Ramón Suárez González, Under-Secretary of the Interior.

Official Gazette [Diario Oficial] No. 31370  
17 September 1982

E/NL.1983/22

MINISTRY OF THE TREASURY. LAW NO. 18,164 INTRODUCES  
CHANGES TO THE CUSTOMS LEGISLATION

The Governing Junta of the Republic of Chile has approved the following

Draft Law

Article 1. [OMITTED]

Article 2. For the customs clearance, for any destination, of food products of any kind; of toxic substances or substances dangerous to health; of pharmaceutical products, foods for medical use and cosmetics; and of addictive

narcotic drugs and psychotropic substances, the National Customs Service shall require a certificate, issued by the appropriate Health Service, specifying the authorized site at which the goods in question are to be stored, the route and the conditions of transport that are to apply to the transfer of said goods from the enclosed customs area to the indicated storage site.

The Health Services shall rule on the certificate referred to in the preceding paragraph within three working days, at the latest, from the date of the application. In the event the Services reject the application, they shall cite the relevant reasons in their ruling.

In the case of animal or vegetable food products or by-products, the National Customs Service shall likewise require the certificate referred to in the preceding article.

Article 3. Once the processing of the destination document has been completed and the goods have been removed from the primary customs area, they shall be stored under the responsibility of the consignee, who may not use, consume, sell, transfer or dispose of them in any way without having first obtained the authorization and approval required under the legislation in force. The appropriate Health Services and the Agricultural and Animal Husbandry Service shall issue a report, either granting the authorization or approval, denying it or fixing a safety period in order that the necessary inspections in respect of human, animal or plant health, as appropriate, may be carried out in the form and under the conditions stipulated in the relevant special legislation. During this period, the goods in question may not be marketed.

The report referred to in the preceding paragraph must be issued within three working days from the date on which the interested party informs the appropriate authorities of the arrival of the goods at the storage site.

Without prejudice to any other sanctions or measures that may be provided for under the legislation in force, the use of a route, of a storage site or of transport conditions other than those specified in the certificate referred to in articles 1 and 2 of this Law, as well as a violation of the prohibitions to which this article refers, shall be punishable by a fine of from 10 to 1,000 monthly tax units.

The fine referred to in the preceding paragraph shall be applied by the director of the appropriate oversight agency. This fine shall be imposed, and may be appealed, in the manner and under the conditions laid down in the statutes of the respective Services.

Article 4. The Chilean Institute of Public Health, the Health Services and the Agricultural and Animal Husbandry Service may exercise all the inspection powers entrusted to them under the law within the storage areas indicated in the certificate issued in accordance with articles 1 and 2 of this Law. The issue of these certificates and the performance of inspections within the private storage areas shall not affect the authority of the Chilean Institute of Public Health, the Health Services and the Agricultural and Animal Husbandry Service to additionally perform prior checks at the primary customs jurisdiction zones.

Article 5. The provisions of the preceding articles shall be applied even in the case of non-processed or non-industrialized products or products imported into the country for the first time. Similarly, with respect only to the procedure for the removal of the goods from the authority of the National Customs Service, the provisions of articles 1 to 4 of this Law shall take precedence over those special provisions in which the legislation specifies a different procedure.

Article 6. The following changes are made to Decree Law No. 341 of the Ministry of the Treasury of 1971, which established the amended and co-ordinated text of Decree Laws Nos. 1,055 and 1,233 of 1975; 1,611 of 1976; and 1,698 of 1977, regarding Free Zones and Warehouses:

1. Paragraph 1 of article 1 is replaced by the following: "The establishment of Free Zones at Iquique and Punta Arenas is authorized."
2. Item (b) of article 2 is deleted.
3. In article 3, the words "as well as the Free Warehouses" are deleted, and [Translator's note: The remaining changes referred to under this point are of a grammatical nature only and have no effect on the English translation].
4. The words "and Free Warehouses" are replaced by the word "Free" in articles 4, 6, 7, 9 and 10, paragraph 2; in articles 11, 13, 24 and 25, paragraph 1; and in Titles II, III and VI.
5. The words "and Free Warehouses" are deleted in articles 8 and 22.
6. The words "or Free Warehouses" are replaced by the word "Free" in article 10, paragraph 1, and in articles 23 and 25, paragraph 2.
7. The words "and Free Warehouse" are eliminated in item (h) of article 12.
8. The expression "and Warehouses" is deleted in article 24, paragraph 2.
9. Article 34 is deleted.

Article 7. The following changes are made to Decree Law No. 3,475 of 1980:

1. Paragraph 7 of article 3 is replaced by the following: "Except in the case of the imports referred to in article 24, items 5 and 10, of this Law, there shall be no exemptions from this tax."
2. The following item 10 is added to article 24:  

"10. Documents required for the import of goods brought into the country under the exemptions established in article 35, paragraph 23, of Law No. 13,039."

Article 8. Article 8 of Law No. 12,401 is deleted.

Transitional article. Goods that have been imported prior to the publication of this Law or that arrive in the country within 90 days of its entry into force and that are subsequently re-exported by the same importer, unused and without having been marketed, shall give rise to an entitlement to a tax credit equal to the amount of the customs duties paid at the time of their import, following the deduction of the tax established in article 3 of Decree Law No. 3,475 of 1980, as credited to these customs duties.

This credit shall be granted in the form of a certificate issued by the National Customs Service. Its amount shall be expressed in United States dollars, it shall be made out in the name of the payee and shall be non-transferable, and it may only be used for the payment of customs duties incurred as the result of subsequent imports.



In the case of imports subject to conditions of deferred duty payments, the credit shall be granted only for the amount actually paid for the goods exported, with the balance of the outstanding debt for the party in question cancelled by the National Customs Service.

This tax credit shall lapse within five years of the date on which the certificate in question is granted.

Regulations issued by the Ministry of the Treasury shall specify the time periods, conditions and modalities for the application of the provisions laid down in the preceding paragraphs.

JOSE T. MERINO CASTRO, Admiral, Commander-in-Chief of the Navy, Member of the Governing Junta. FERNANDO MATTHEI AUBEL, General of the Air Force, Commander-in-Chief of the Air Force, Member of the Governing Junta. CESAR MENDOZA DURAN, Director-General of the Carabineros, Member of the Governing Junta. CESAR RAUL BENAVIDES ESCOBAR, Lieutenant General of the Army, Member of the Governing Junta.

Having approved the legislation transcribed above, I hereby sign it into law, thus promulgating it for observance as a Law of the Republic.

To be recorded at the Office of the Comptroller-General of the Republic, published in the Official Gazette and included in the Official List of Laws of that Office.

Done in Santiago, Chile, on seven September nineteen hundred and eighty-two. AUGUSTO PINOCHET UGARTE, General of the Army and President of the Republic.

Rolf Lüders Schwarzenberg, Minister of the Treasury.

Transcribed for you by Enrique Seguel Morel, Colonel, Under-Secretary of the Treasury.

Republic of Chile  
Ministry of Health  
Chilean Institute of Public Health  
National Control Department

E/NL.1983/23

No. 1707. Santiago, 21 September 1982

Considering the requirement that the addictive products covered by this regulation are to be sold only "under filed medical prescription", the provisions of the Public Health Code, and Decree Law No. 725 of 1968, and

Bearing in mind the powers vested in me under article 39, item (b), of Decree Law No. 2763 of 1979 and Supreme Decree No. 79 of 1980, both of the Ministry of Health, and Ruling No. 027 of 1980 of the Chilean Institute of Public Health,

I hereby issue the following

RULING

1. It is ordered that addictive pharmaceutical products subject to the requirement that they may be sold only "under filed medical prescription" are to be covered by Ruling No. 1324 of 3 October 1977 of the Director General for Health, in the

sense that the distribution of MEDICAL SAMPLES and the COMMERCIAL PROMOTION of these products at any level are PROHIBITED.

2. It is established that the special pharmaceutical products that are mentioned below and that contain the active principle identified are covered by the provisions of this Ruling:

<u>Name of the speciality</u>	<u>Active principle</u>
Incolme tablets	Phenproporex
Suralgon tablets	Phenproporex
Sinapet capsules	Phenproporex
Salcal tablets	Phenproporex
Plumivin tablets	Phenproporex
P-92 capsules	Magnesium pemoline
Deadyn tablets	Pemoline
Filinasma tablets	Amobarbital
Ritalin tablets	Methylphenidate
Alpid tablets	Diethylpropione
Sacin tablets	Diethylpropione
Exacid tablets	Diethylpropione
Sanorex tablets	Mazindol
Darvon compound capsules	Dextropropoxyphene
Sosegon (all pharmaceutical forms)	Pentazocine
Broncacime dragées	Dextromethorfan
Norgidasa syrup	Dextromethorfan
Romilar (all pharmaceutical forms)	Dextromethorfan
Torfan-H (all pharmaceutical forms)	Dextromethorfan

TO BE RECORDED AND COMMUNICATED

(Signed) Dr. Raquel González Díez  
Chief, National Control Department

Republic of Chile  
Ministry of Health  
Chilean Institute of Public Health  
National Control Department

E/NL.1983/24

RULING No. 2539 ESTABLISHES THAT PHARMACEUTICAL SPECIALITIES CONTAINING CODEINE SHALL BE SOLD TO THE PUBLIC ON THE BASIS OF THE "RETAINED-PRESCRIPTION" SYSTEM

Santiago, 19 November 1982

Considering Resolution II/3 of the Second Conference of the South American Agreement on Narcotic Drugs and Psychotropic Substances, held in Guayaquil in October 1980; the advisability of implementing that recommendation with respect to the sales conditions governing pharmaceutical specialities containing Codeine; and the provisions of articles 2, 46, 55 and 64 of Supreme Decree No. 435 of 1981 of the Ministry of Health; and

Bearing in mind the powers vested in me under articles 36 and 37, item (b), of Decree Law No. 2763 of 1979,

I hereby issue the following

RULING

1. Pharmaceutical specialities containing codeine or its salts, shall be sold to the public under the retained-prescription system.
2. This condition of sale (R.R.) 1/ must appear on the labels of such products as are authorized on the date this Resolution comes into effect or as may be registered in the future. To this end, the interested parties shall submit the new labels for approval by this Institute within 30 days of that same date.
3. Pharmaceutical products whose therapeutical indication is "antitussive" and that contain 15 milligrams or less of codeine or its salts per recommended dosage shall be exempted from these provisions.
4. This Ruling shall apply from 1 February 1983.

TO BE RECORDED AND COMMUNICATED

(Signed) Joaquín Larrain Gana  
General of the Army (Ret.)  
Director, Chilean Institute of  
Public Health

Republic of Chile  
Ministry of Health  
Chilean Institute of Public Health  
National Control Department

E/NL.1983/25

Santiago, 19 November 1982

Considering the failure to comply with the requirement that the pharmaceutical product Ipesandrine Drops, Health Registry No. 3898, which contains 0.42 grams of total opium alkaloids per 100 ml of solution and which is produced by the firm Sandoz Farmacéutica Ltda., located at Avda. Zañartu No. 1482 of this city, is to be sold under medical prescription only,

Further considering: That opium is a narcotic drug subject to international and domestic control,

That the drug in question is being improperly used, and

That there are persons addicted to Ipesandrine, and

Bearing in mind the provisions of the Health Code, Decree Law No. 725 of 1968, articles 106 and 107 of the Regulations on Narcotic Drugs, Supreme Decree No. 137/60 of the Ministry of Health, and by virtue of the powers vested in me under article 39, item (b) of Decree Law No. 2763 of 1979 and Supreme Decree No. 79 of 1980 of the Ministry of Health,

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1/ Translator's note: Spanish "Receta Retenida" ("Retained Prescription").

I hereby issue the following

RULING

1. The condition of sale for the product Ipesandrine Solution (drops), authorized under Health Registry No. 3898 on behalf of the firm Sandoz-Farmaceutica Ltda., is changed in the sense that, from the date of this Ruling, its condition of sale is the following: "UNDER PRESCRIPTION CHEQUE".

2. All such boxes and labels as are currently in stock may be sold on condition that an adhesive band stating the new sales regulation is affixed to the package, but it is required that all subsequent production lots must carry a printed statement of the new condition of sale on their labels.

3. It is established that pharmacies may sell their existing stocks as labelled, but subject to the new sales regulation, namely "Prescription Cheque", with each sale to be recorded in the Official Register of Narcotic Drugs.

4. On the date of notification of this Resolution, existing inventories of this product are to be entered in the Official Register of Narcotic Drugs of the Production Laboratory, Drug Stores and Pharmacies.

5. It is ordered that applications for the transfer of the product are to be sent to this Institute, with copies to be transmitted on a monthly basis during the first ten (10) days of each month, in addition to the statistics describing inventories and consumption.

6. Notification of this Ruling is to be made by the chemico-pharmaceutical inspectors of this Department.

TO BE RECORDED AND COMMUNICATED

(Signed) Joaquín Larrain Gana  
General of the Army (Ret.)  
Director, Chilean Institute of  
Public Health