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.

SPAIN
Communicated by the Government of Spain

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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MINISTRY OF HEALTH AND SOCIAL SECURITY

ORDER of 15 January 1981 to include preparations containing tilidine in Schedule I annexed to the 1961 Single Convention on Narcotic Drugs

Sir,

In view of the decision adopted by the United Nations Commission on Narcotic Drugs at its 885th meeting and communicated by the Secretary-General of the United Nations on 31 March 1980, in accordance with the reports and recommendations of the World Health Organization, to include tilidine in Schedule I annexed to the 1961 Single Convention on Narcotic Drugs; and

Bearing in mind the provisions of article 3, paragraph 3(iii) of the Single Convention on Narcotic Drugs, which has been ratified by Spain, and by virtue of the powers conferred by chapter 1, article 2 of Law 17/1967 of 8 April 1967 on narcotic drugs,

The Ministry of Health and Social Security made the following decisions:

1. To include the substance (+)-ethyl \textit{trans}-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate, the international nonproprietary name of which is "tilidine", in Schedule I annexed to the 1961 Single Convention on Narcotic Drugs.

2. Establishments manufacturing or importing tilidine at the time this ministerial Order enters into force shall declare to the General Directorate for Regulation of Pharmacies and Medicines any stocks of tilidine they may possess.

3. Estimates of future manufacture, import and export of tilidine shall be submitted for prior authorization to the General Directorate for Regulation of Pharmacies and Medicines.

4. The storage, sale and distribution of tilidine shall be adapted to conform to the regulations in force for narcotic substances listed in Schedule I of the Single Convention.

5. Laboratories owning patents for pharmaceutical specialities containing tilidine, pharmaceutical depots, pharmacies and hospital dispensaries shall declare to the Narcotics and Psychotropics Control Section their stocks of the pharmaceutical specialities concerned or of tilidine, as the case may be, and shall at the same time record the stocks in the Narcotics Book.

6. Currently marketed pharmaceutical specialities containing this substance at the time this ministerial Order enters into force shall be distributed, prescribed, dispensed and supervised in accordance with the legal requirements applicable to preparations and products in Schedule I of [the Single Convention on] Narcotic Drugs.

7. Within a period of thirty days the laboratories producing pharmaceutical specialities shall adapt their material and equipment for processing preparations containing tilidine in conformity with the provisions regarding narcotic substances.

8. The present ministerial Order shall enter into force on the day following its publication in the \textit{Official Gazette}.

The above is hereby communicated to you for information and action.

Madrid, 15 January 1981

OLIART SAUSSOL

To the Director-General, Regulation of Pharmacies and Medicines
MINISTRY OF HEALTH AND SOCIAL SECURITY

ORDER of 11 February 1981 to include preparations containing sufentanil in Schedule I to the 1961 Single Convention on Narcotic Drugs

Sir,

In view of the decision adopted by the United Nations Commission on Narcotic Drugs at its 885th meeting and communicated by the Secretary-General of the United Nations on 31 March 1980, in accordance with the reports and recommendations received from the World Health Organization, to include sufentanil in Schedule I to the 1961 Single Convention on Narcotic Drugs;

Bearing in mind the provisions of article 3, paragraph 3(iii) of the Single Convention on Narcotic Drugs, which has been ratified by Spain, and by virtue of the powers conferred by chapter I, article 2, of Law 17/1967 of 8 April 1967 on narcotic drugs;

The Ministry of Health and Social Security has made the following arrangements:

1. To include the substance N-[4-(methoxymethyl)-1-[2-(2-thienyl)-ethyl]-4-piperidyl] propionanilide, the international nonproprietary name of which is sufentanil, in Schedule I to the 1961 Single Convention on Narcotic Drugs.

2. Establishments manufacturing or importing sufentanil at the time this ministerial Order enters into force shall declare to the Office of the General Directorate for Regulation of Pharmacies and Medicines any stocks of sufentanil they may possess.

3. Estimates of future manufacture, import and export of sufentanil shall be submitted for prior authorization to the Office of the Director-General, Regulation of Pharmacies and Medicines.

4. The storage, sale and distribution of sufentanil shall be adapted to conform to the regulations in force for narcotic substances listed in Schedule I of the Single Convention.

5. Laboratories owning patents for pharmaceutical specialities containing sufentanil, pharmaceutical depots, pharmacies and hospital dispensaries shall declare to the Narcotics and Psychotropics Control Section their stocks of the pharmaceutical specialities concerned or of sufentanil, as the case may be, and shall at the same time record the stocks in the narcotics book.

6. Currently marketed pharmaceutical specialities containing this substance at the time this ministerial Order enters into force shall be distributed, prescribed, dispensed and supervised in accordance with the legal requirements applicable to preparations and products in Schedule I of Narcotic Drugs.

7. Within a period of 30 days the laboratories producing pharmaceutical specialities shall adapt their equipment for preparations containing sufentanil in conformity with the provisions regarding narcotic substances.

8. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby communicated to you for information and action.

Madrid, 11 February 1981.

OLIART SAUSSOL

To the Director-General, Regulation of Pharmacies and Medicines
MINISTRY OF HEALTH AND SOCIAL SECURITY

ORDER of 11 February 1981 to include the substances TCP, PHP or PCPY and PCE in Schedule I to the 1971 Convention on Psychotropic Substances

Sir,

In view of the decision adopted by the United Nations Commission on Narcotic Drugs at its 885th meeting and communicated by the Secretary-General of the United Nations on 31 March 1980, in accordance with the reports and recommendations received from the World Health Organization, to include TCP, PHP or PCPY and PCE in Schedule I of the 1971 Convention on Psychotropic Substances;

Bearing in mind the provisions of article 2, paragraph 7, of this Convention, which has been ratified by Spain, and by virtue of the powers conferred by the final provision of Royal Decree 2829/1977 of 6 October 1977,

The Ministry of Health and Social Security has made the following arrangements:

1. To include the substances 1-[(1-(2-thienyl)cyclohexyl] piperidine, the nonproprietary name of which is TCP, 1-(1-phenylcyclohexyl)pyrrolidine, the nonproprietary name of which is either PHP or PCPY, and N-ethyl-l-phenylcyclohexylamine, the nonproprietary name of which is PCE, in Schedule I of annex 1 to Royal Decree 2829/1977 of 6 October 1977 regulating psychotropic substances and preparations.

2. In accordance with the provisions of article 2 of the aforesaid Royal Decree, the use, manufacture, import, export, transit, trade, distribution and storing of said substances, as well as preparations containing them, are prohibited and subject to the Law of Contraband.

Consequently, within a period of 30 days from the date on which the present ministerial Order comes into force any establishment or individual in possession of such substances or their preparations shall deposit them with the Narcotics and Psychotropics Control Section of the General Directorate for Regulation of Pharmacies and Medicines or the Provincial Pharmacy Inspectorsates of the regional offices of the Ministry.

3. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby communicated to you for information and action.

Madrid, 11 February 1981

OLIART SAUSSOL

To the Director-General, Regulation of Pharmacies and Medicines

MINISTRY OF HEALTH AND SOCIAL SECURITY

ORDER of 11 February 1981 to include the substance mecloqualone in Schedule II to the 1971 Convention on Psychotropic Substances

Sir,

In view of the decision adopted by the United Nations Commission on Narcotic Drugs at its 885th meeting and communicated by the Secretary-General of the United Nations on 31 March 1980, in accordance with the reports and recommendations received from the World Health Organization, to include mecloqualone in Schedule II to the 1971 Convention on Psychotropic Substances;

Bearing in mind the provisions of article 2, paragraph 7, of the said Convention, which has been ratified by Spain, and by virtue of the powers conferred by the final provision of Royal Decree 2829/1977 of 6 October 1977,

The Ministry of Health and Social Security has made the following arrangements:
1. To include the substance 3-(o-chlorophenyl)-2-methyl-4-(3H)-quinazolinone, the international nonproprietary name of which is mecloqualone, in Schedule II of Annex 1 to Royal Decree 2829/1977 of 6 October 1977 regulating psychotropic medicinal substances and preparations.

2. Within a period of 30 days from the date on which the present ministerial Order enters into force, establishments manufacturing, importing or exporting, distributing or dispensing the substance in question and preparations containing it shall modify their procedures and adapt their preparations to conform with the legal requirements in force for products included in Schedule II.

3. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby communicated to you for information and action.

Madrid, 11 February 1981

OLIART SAUSSOL

To the Director-General, Regulation of Pharmacies and Medicines.

MINISTRY OF HEALTH AND CONSUMER AFFAIRS

ORDER of 18 February 1982 to include preparations containing dextropropoxyphene in Schedule II annexed to the Single Convention on Narcotic Drugs of 1961

In view of the decision adopted by the United Nations Commission on Narcotic Drugs at its 885th meeting and communicated by the Secretary-General of the United Nations on 31 March 1980, in accordance with the reports and recommendations of the World Health Organization, to include dextropropoxyphene in Schedule II of the 1961 Single Convention on Narcotic Drugs; and

Bearing in mind the provisions of article 3, paragraph 3(iii) of the Single Convention on Narcotic Drugs, which has been ratified by Spain, and by virtue of the powers conferred by chapter 1, article 2 of Law 17/1967 of 8 April 1967 on narcotic drugs,

The Ministry of Health and Consumer Affairs has decided to provide as follows:

1. To include the substance (+)-(+-)-4-dimethylamino-1,2-diphenyl-3-methyl-2-butanol propionate, the international nonproprietary name of which is "dextropropoxyphene", in Schedule II annexed to the 1961 Single Convention on Narcotic Drugs.

2. Establishments manufacturing or importing dextropropoxyphene at the time this ministerial Order enters into force shall declare to the General Directorate for Regulation of Pharmacies and Medicines any stocks of this product they may possess.

3. Estimates of future manufacture, import or export of dextropropoxyphene shall be submitted for prior authorization to the General Directorate for Regulation of Pharmacies and Medicines.

4. The storage, sale and distribution of dextropropoxyphene shall be adapted to conform to the regulations in force for narcotic substances listed in Schedule II of the Single Convention.

5. Currently marketed pharmaceutical specialities containing this substance at the time this ministerial Order enters into force shall be distributed, prescribed, dispensed and supervised in accordance with the legal requirements for preparations and products in Schedule II of [the Single Convention on] Narcotic Drugs.

6. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

Madrid, 18 February 1982

NUNEZ PEREZ
MINISTRY OF HEALTH AND CONSUMER AFFAIRS

ORDER of 20 May 1983 to regulate methadone treatments

Gentlemen,

In view of the nature of methadone treatment and the hygienic and social circumstances of the individuals to which this treatment is applied, it is desirable for its use in medical practice to be subjected to certain requirements and precautions. Law 17/1967 of 8 April 1967 establishing regulations for the control of narcotic drugs authorizes the State in article 1 to regulate the prescription, use and consumption of such substances.

Pursuant to this Law, the Ministry of Health and Consumer Affairs has made the following decisions:

1. Treatments of opiate-dependent addicts with methadone must be registered in a withdrawal record, authenticated by a treatment schedule worked out for each patient individually by the attending physicians, in which the use of the narcotic referred to must be justified.

2. The treatment schedule referred to in the previous paragraph is required to contain:

   (a) An evaluation of the patient's physical, mental, family, employment and social situation at the beginning of the treatment;

   (b) A report on the nature and dosage of the narcotic drugs consumed at the beginning of the addiction, the circumstances in which the addiction began, the development of the addiction and the quantity of heroin taken at the time of starting the treatment;

   (c) Recommendations for medical attention, including monitoring the patient's physical and nutritional state and testing for infectious diseases;

   (d) Analytical checks enabling the patient's degree of withdrawal to be estimated; and

   (e) All such health and welfare measures as would, in the view of the attending physician, be desirable or necessary for the treatment of the patient.

3. The treatment plan referred to above must be submitted by the attending physician to the appropriate Public Health Services. Attending physicians prescribing methadone treatments shall inform these services on the progress of the treatment every three months. All data referred to in the foregoing sections are to be treated as confidential.

4. The narcotic drugs control services of the Ministry of Health and Consumer Affairs shall issue identity booklets authorizing extra doses of methadone only if a note from the Public Health services is attached to the basic application document certifying that the individual treatment plan and, where appropriate, the three-monthly reports have been submitted to them. The narcotic drug control services of the Ministry of Health and Consumer Affairs are empowered, either of their own accord or at the request of the attending physician, to regulate and supervise the prescription, possession, use and consumption of methadone.

5. Prescriptions of methadone for the treatment of drug addicts shall be made up in the form of solutions for immediate intake and the use of injection capsules or non-liquid oral forms in making up such prescriptions is prohibited.

6. The validity of the extra-dose identity booklet provided for in the ministerial Orders of 6 February 1962 and 31 August 1935 is limited to thirty days. The booklet shall consist of not more than thirty sheets including supporting documents.

Final provision. The Office of the Under-Secretary for Health and Consumer Affairs is empowered to issue the detailed regulations for executing the provisions of this ministerial Order.

The above is hereby transmitted to you.

Madrid, 20 May 1983

LLUCH MARTIN

To the Under-Secretary, the Director-General, Regulation of Pharmacies and Medicines and the Director-General for Public Health.
MINISTRY OF HEALTH AND CONSUMER AFFAIRS

ORDER of 22 July 1983 to provide for the inclusion of methaqualone in Schedule II annexed to the 1971 Convention on Psychotropic Substances

Sir,

In view of the decision taken by the United Nations Commission on Narcotic Drugs at its 874th meeting and communicated by the Secretary-General of the United Nations on 28 March 1979 to transfer methaqualone from Schedule IV to Schedule II annexed to the Convention on Psychotropic Substances of 1971, in accordance with the reports and recommendations of the World Health Organization; and

Bearing in mind the provisions of article 2, paragraph 7 of that Convention, which has been ratified by Spain, and by virtue of the powers conferred upon us by the final provision of Royal Decree 2829/1977 of 6 October 1977,

The Ministry of Health and Consumer Affairs has made the following decisions:

1. To transfer the substance 2-methyl-3-o-tolyl-4(3H)-quinazolinone, which has the international nonproprietary name "methaqualone" and previously appeared as one of the substances of Schedule IV in Annex I of Royal Decree 2829/1977 of 6 October 1977 regulating psychotropic substances, to Schedule II of Annex I.

2. Within a period of thirty days commencing from the entry into force of the present ministerial Order, establishments manufacturing, importing and/or exporting, distributing and dispensing the substance referred to or preparations containing it shall modify their business procedures and adapt their products to conform with the legal requirements in force for products included in Schedule II.

3. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby transmitted to you for information and action.

Madrid, 22 July 1983

LLUCH MARTIN

To the Director-General, Regulation of Pharmacies and Medicines

MINISTRY OF HEALTH AND CONSUMER AFFAIRS

ORDER of 22 July 1983 to provide for the inclusion of phendimetrazine and phentermine in Schedule IV annexed to the 1971 Convention on Psychotropic Substances

Sir,

In view of the decision taken by the United Nations Commission on Narcotic Drugs at its 899th meeting and communicated by the Secretary-General of the United Nations on 3 April 1981 to include phendimetrazine and phentermine in Schedule IV annexed to the Convention on Psychotropic Substances of 1971, in accordance with the reports and recommendations of the World Health Organization; and

Bearing in mind the provisions of article 2, paragraph 7 of that Convention, which has been ratified by Spain, and by virtue of the powers conferred upon us by the final provision of Royal Decree 2829/1977 of 6 October 1977,

The Ministry of Health and Consumer Affairs has made the following decisions:

1. To transfer the substance (+)-3,4-dimethyl-2-phenylmorpholine, the international nonproprietary name of which is "phendimetrazine", and the substance α,ω-dimethylphenethylamine, the international nonproprietary name of which "phentermine", from Annex 2 of the Royal Decree 2829/1977 of 6 October 1977 regulating psychotropic substances and medicinal preparations to Schedule IV in Annex I of that Decree.
2. Within a period of thirty days commencing from the entry into force of the present ministerial Order, firms manufacturing, importing and/or exporting, distributing and dispensing the substances referred to shall modify their business procedures and adapt their products to conform with the legal requirements in force for products in Schedule IV.

3. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby transmitted to you for information and action.

Madrid, 22 July 1983

LLUCH MARTIN

To the Director-General, Regulation of Pharmacies and Medicines

MINISTRY OF HEALTH AND CONSUMER AFFAIRS

ORDER of 22 July 1983 to provide for the inclusion of benzphetamine and mazindol in Schedule IV annexed to the 1971 Convention on Psychotropic Substances

Sir,

In view of the decision taken by the United Nations Commission on Narcotic Drugs at its 899th meeting and communicated by the Secretary-General of the United Nations on 3 April 1981 to include benzphetamine and mazindol in Schedule IV annexed to the Convention on Psychotropic Substances of 1971, in accordance with the reports and recommendations of the World Health Organization; and

Bearing in mind the provisions of article 2, paragraph 7 of that Convention, which has been ratified by Spain, and by virtue of the powers conferred upon us by the final provision of Royal Decree 2829/1977 of 6 October 1977,

The Ministry of Health and Consumer Affairs has made the following decisions:

1. To include the substance N-benzyl-N-<j>dimethylphenethylamine, the international nonproprietary name of which is "benzphetamine", and the substance 5-<j>di</j>hydro-3Himidazo[2,1-l]isoindol-5-01, the international nonproprietary name of which is "mazindol", in Schedule IV of Annex 1 to Royal Decree 2829/1977 of 6 October 1977 regulating psychotropic substances and medicinal preparations.

2. Within a period of thirty days commencing from the entry into force of the present ministerial Order, establishments manufacturing, importing and/or exporting, distributing and dispensing the substances referred to shall modify their business procedures and adapt their products to conform with the legal requirements in force for products in Schedule IV.

3. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby transmitted to you for information and action.

Madrid, 22 July 1983

LLUCH MARTIN

To the Director-General, Regulation of Pharmacies and Medicines
RESOLUTION of 2 December 1983 of the General Directorate for Regulation of Pharmacies and Medicines to establish standards for the return of pharmaceutical specialities containing narcotic drugs in Schedule I of the 1961 Convention on Narcotic Drugs

There have been fairly frequent requests for detailed instructions on the manner of applying Royal Decree 726/1982 of 17 March 1982 on expiry and return to the pharmaceutical specialities containing substances included in Schedule I of the 1961 Single Convention on Narcotic Drugs, since stocks of them are subject to special control.

With a view to unifying the criteria and establishing a valid system to combine the possibility of return with rigorous control of stocks of narcotic drugs laid down in article 60 of the Single Convention, the General Directorate for Regulation of Pharmacies and Medicines, by virtue of its powers under legislation in force, has decided as follows:

1. In accordance with the provisions of article 2 of Royal Decree 726/1982, the batches of pharmaceutical specialities which contain substances in Schedule I of the 1961 Single Convention on Narcotic Drugs may not be used for therapeutic purposes after their expiry date.

2. Items from expired batches must be returned to the laboratory holding the registration or destroyed with the authorization of the appropriate provincial pharmacies service.

3. The items shall be returned against official receipts established for the purpose. The official receipts shall certify the receipt and exit of items noted thereupon and shall remain on file with the relevant pharmaceutical establishments.

Any return of pharmaceutical specialities containing narcotic drugs must be communicated to the appropriate provincial pharmacies services.

4. The destruction of expired items shall be carried out in the presence of the provincial pharmacies services and the corresponding certificate shall be issued. Notification of these proceedings shall be made to the Narcotics and Psychotropics Control Section of the General Directorate for Regulation of Pharmacies and Medicines.

TRANSITIONAL PROVISION

Until the General Directorate produces the specific official receipts for return, use shall be made of the receipts currently valid for orders, clearly and visibly marked by the pharmaceutical establishment with the word "Return".

The above is hereby transmitted to you.

Madrid, 2 December 1983

The Director-General
Félix Lobo Alén

To the Under-Directors-General for Pharmaceutical Establishments and Assistance and Pharmaceutical Control
MINISTRY OF HEALTH AND CONSUMER AFFAIRS

RESOLUTION of 4 April 1984 by the General Directorate for Regulation of Pharmacies and Health Products to establish additional regulations for the control of certain psychotropic substances


In their capacity as health service establishments and professional officers, pharmaceutical laboratories and their technical directors are required to inform the health authorities of any facts known to them concerning improper use of psychotropic substances and preparations and also concerning inadequately justified increases in the use of such products.

In view of the fact that a considerable increase has been noted in cases of diversion of pharmaceutical specialities containing psychotropic substances to non-therapeutic purposes, the General Directorate for Regulation of Pharmacies and Health Products considers it necessary to adopt certain special control measures for them.

I have accordingly resolved, pursuant to the powers invested in me by article 5 of Law 17/1967 of 8 April 1967 and article 4 of Royal Decree 2829/1977 of 6 October 1977, as follows:

1. Pharmaceutical specialities containing psychotropic substances listed in the schedule attached to this Resolution and shown as being administered by the method indicated in it shall be included in accounting systems that enable movements in and out, and also the stocks of these products on hand in the pharmaceutical establishments, to be ascertained.

2. To facilitate control of the production, distribution and dispensation of these items, and irrespective of the requirements imposed by other legislation in force with regard to narcotics drugs and psychotropic substances, the following additional measures shall be adopted:

   (a) Laboratories producing pharmaceutical specialities shall send to the Office of the Assistant Director-General for Pharmaceutical Control quarterly, in addition to the statement of batches provided for in Decree 2828/1965 of 14 August 1965, information on the pharmaceutical specialities to which this Resolution applies that were sold in the period and to whom they were sold. This information shall be supplied within the month following the end of the quarterly period.

   (b) Pharmaceutical depots shall keep available for the Pharmaceutical Inspection Services the documentation necessary to enable the origin, destination and quantity of pharmaceutical specialities specified by the Office of the Assistant Director-General for Pharmaceutical Control as containing substances listed in the attached schedule to be ascertained.

3. Special attention is again drawn to the compulsory requirement that pharmaceutical specialities containing psychotropic substances listed in the annexes to Royal Decree 2829/1977 of 6 October 1977 and/or narcotic drugs in Schedules II and III of the 1961 Convention may be dispensed only against medical prescription and entry in the prescription book.

For the attention of the Assistant Director-General for Pharmaceutical Control.

Madrid, 4 April 1984.

The Director-General
Félix Lobo Alén

SCHEDULE

Method of administration: oral and parenteral.

Psychotropic substances:


(b) Bultalbital
    Clorazepate
    Chlordiazepoxide
    Dextropropoxyphene
    Diazepam
    Flunitrazepam
MINISTRY OF HEALTH AND CONSUMER AFFAIRS

ORDER of 30 May 1984 to provide for the inclusion of pentazocine in Schedule III annexed to the Convention on Psychotropic Substances concluded in Vienna on 21 February 1971

Sir,

In view of the decision adopted by the United Nations Commission on Narcotic Drugs at its 941st meeting, on 7 February 1984, and communicated by the Secretary-General of the United Nations on 28 March 1984, in accordance with the reports and recommendations of the World Health Organization, to include pentazocine in Schedule III annexed to the Convention on Psychotropic Substances concluded in Vienna on 21 February 1971 and published in the [Spanish] Official Gazette No. 218 of 10 September 1976; and

Bearing in mind the provisions of article 2, paragraph 7, of that Convention, which has been ratified by Spain, and by virtue of the powers conferred by the final provision of Royal Decree 2829/1977 of 6 October 1977,

The Ministry of Health and Consumer Affairs has made the following decisions:

1. To include the substance 1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butene)-2,6-methano-3-benzazocin-8-ol, the [international nonproprietary] name of which is "pentazocine", in Schedule III of the Convention on Psychotropic Substances [and] in Schedule III of Annex 1 of Royal Decree 2829/1977 of 6 October 1977.

2. Within a period of thirty days commencing from the entry into force of the present ministerial Order, establishments manufacturing, importing, exporting, distributing or dispensing the substance referred to shall modify their business procedures in conformity with the legal requirements imposed in respect of psychotropic substances listed in Schedule III of Annex 1 to Royal Decree 2829/1977 by that Decree and by the ministerial Order of 14 January 1981.

3. Those laboratories that are registered as licenced to produce pharmaceutical specialities containing pentazocine shall modify their material and equipment for processing these specialities within a period of ninety days.

4. The prescription, dispensation and control of these pharmaceutical specialities shall be carried out in conformity with the provisions of Royal Decree 2829/1977 of 6 October 1977.

5. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby communicated to you for information and action.

Madrid, 30 May 1984

LLUCH MARTIN

To the Director-General, Regulation of Pharmacies and Health Products
ORDER of 30 May 1984 to provide for the inclusion of 33 benzodiazepines in Schedule IV annexed to the Convention on Psychotropic Substances concluded in Vienna on 21 February 1971

Sir,

In view of the decision adopted by the United Nations Commission on Narcotic Drugs at its 941st meeting, on 7 February 1984, and communicated by the Secretary-General of the United Nations on 29 March 1984, in accordance with the reports and recommendations of the World Health Organization, to include 33 benzodiazepines in Schedule IV annexed to the Convention on Psychotropic Substances concluded in Vienna on 21 February 1971 and published in the [Spanish] Official Gazette No. 218 of 10 September 1976; and

Bearing in mind the provisions of article 2, paragraph 7 of that Convention, which has been ratified by Spain, and by virtue of the powers conferred by the final provision of Royal Decree 2829/1977 or 6 October 1977,

The Ministry of Health and Consumer Affairs has made the following decisions:

1. To include the substances in Schedule IV annexed to the Convention on Psychotropic Substances and Schedule IV of Annex 1 of Royal Decree 2829/1977 of 6 October 1977:

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<th>Substance 1</th>
<th>Substance 2</th>
<th>Substance 3</th>
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<td>Alprazolam</td>
<td>Estazolam</td>
<td>Medazepam</td>
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<td>Bromazepam</td>
<td>Ethyl loflazepate</td>
<td>Nimetzapam</td>
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<tr>
<td>Camazepam</td>
<td>Fludiazepam</td>
<td>Nortrazepam</td>
</tr>
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<td>Chlordiazepoxide</td>
<td>Flunitrazepam</td>
<td>Oxazepam</td>
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<tr>
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<td>Halazepam</td>
<td>Prazepam</td>
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<tr>
<td>Clorazepate</td>
<td>Haloxazolam</td>
<td>Temazepam</td>
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<tr>
<td>Clotiazepam</td>
<td>Ketazolam</td>
<td>Triazocam</td>
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<td>Lorazepam</td>
<td>Diazepam</td>
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<tr>
<td>Delorazepam</td>
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<tr>
<td>Diazepam</td>
<td>Lorazepam</td>
<td>Diazepam</td>
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</table>

2. Within a period of thirty days commencing from the entry into force of the present ministerial Order, establishments manufacturing, importing, exporting, distributing or dispensing the substance referred to shall modify their business procedures in conformity with the legal requirements imposed in respect of psychotropic substances listed in Schedule IV of Annex 1 to Royal Decree 2829/1977 by that Decree and by the ministerial Order of 14 January 1961.

3. Those laboratories that are registered as licenced to produce pharmaceutical specialities containing substances covered by this Order shall modify their material and equipment for processing these specialities within a period of ninety days.

4. The prescription, dispensation and control of these pharmaceutical specialities shall be carried out in conformity with the provisions of Royal Decree 2829/1977 of 6 October 1977.

5. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

Communicated to you

Madrid, 30 May 1984

LLUCH MARTIN

To the Director-General, Regulation of Pharmacies and Health Products
ORDER of 30 May 1984 to provide for the inclusion of alfentanil in Schedule I annexed to the Single Convention on Narcotic Drugs, 1961

Sir,

In view of the decision taken by the United Nations Commission on Narcotic Drugs at its 940th meeting, on 6 February 1984, and communicated by the Secretary-General of the United Nations on 27 March 1984 to include alfentanil in Schedule I of the Single Convention on Narcotic Drugs of 1961, in accordance with the reports and recommendations of the World Health Organization; and

Bearing in mind the provisions of section II of paragraph 3 of the Single Convention on Narcotic Drugs, which has been ratified by Spain, and by virtue of the powers conferred by chapter I, article 2 of Law 17/1967 of 8 April 1967 on narcotic drugs, the Ministry of Health and Consumer Affairs has decided to provide as follows:

1. To include the substance N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidinyl]-N-phenylpropanamide monohydrochloride, the international nonproprietary name of which is "alfentanil", in Schedule I annexed to the Single Convention on Narcotic Drugs, 1961, and to that Convention as amended by the 1972 Protocol.

2. Establishments manufacturing or importing alfentanil at the time that this ministerial Order enters into force shall declare such stocks of the product as they may possess to the Office of the Director-General, Regulation of Pharmacies and Health Products.

3. Estimates of future manufacture, import or export of alfentanil shall be submitted for prior authorization to the Office of the Director-General, Regulation of Pharmacies and Health Products.

4. The storage, sale and distribution of alfentanil shall be adapted to conform to the regulations in force for narcotic substances in Schedule I of the Single Convention.

5. Laboratories licenced to produce pharmaceutical specialities containing alfentanil, pharmaceutical depots, pharmacies and hospital dispensaries shall declare to the Narcotics and Psychotropics Control Section of the General Directorate for Regulation of Pharmacies and Health Products their stocks of such specialities or products, as the case may be, and shall at the same time record the stocks in the Narcotics Book.

6. Currently marketed pharmaceutical specialities containing alfentanil shall be distributed, prescribed, dispensed and supervised in accordance with the legal requirements for preparations and products in Schedule I of the Single Convention.

7. Laboratories producing pharmaceutical specialities shall within a period of thirty days undertake the adaptation of their processing material and equipment for preparations containing alfentanil to conform to the requirements for narcotic drugs.

8. The present ministerial Order shall enter into force on the day following its publication in the Official Gazette.

The above is hereby transmitted to you for information and action.

Madrid, 30 May 1984

LLUCH MARTIN

To the Director-General, Regulation of Pharmacies and Health Products