



UNITED NATIONS

E/NL 1953/35-41
19 March 1953

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE
CONVENTION OF 13 JULY 1931 FOR LIMITING THE MANUFACTURE
AND REGULATING THE DISTRIBUTION OF NARCOTIC DRUGS, AS
AMENDED BY THE PROTOCOL OF 11 DECEMBER 1946

ITALY

COMMUNICATED BY THE GOVERNMENT OF
ITALY

NOTE BY THE SECRETARY-GENERAL

In accordance with Article 21 of the Convention of 13 July 1931 for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, as amended by the Protocol of 11 December 1946, the Secretary-General has the honour to communicate the following legislative texts.

New York, 1953

ACT NO. 301 OF 20 APRIL 1951

Amendment to the Act No.631 of 10 August 1950 to control the manufacture and sale of the esters of methyl-phenyl-piperidine-carboxylic acid, commonly known as dolantin or mephidine, and of other preparations having the same effect as morphine.

The Chamber of Deputies and the Senate of the Republic have approved;

PRESIDENT OF THE REPUBLIC
Promulgates

the following Act:

Article 1

Article 1 of Act No.631 of 10 August 1950 shall be replaced by the following text:

"For the purposes of the Consolidated Public Health Acts, approved by Royal Decree No.1265 of 27 July 1934, of the Consolidated Public Security Acts, approved by Royal Decree No.773 of 18 June 1931, and of Royal Legislative Decree No.151, of 15 January 1934, containing new regulations on narcotic drugs, the following substances are classified as toxic substances having narcotic effects:

- (1) the esters of methyl-phenyl-piperidine-carboxylic acid, their derivatives and preparations;
- (2) d-1-2-dimethylamino-4, 4-diphenyl-heptanone-5, its derivatives and preparations".

Article 2

The Office of the High Commissioner for Hygiene and Public Health is authorized for a period of two years to promulgate decrees extending the provisions of the preceding article to other preparations having the same narcotic effect as morphine.

Article 3

The present Act shall enter into force on the day following the day of its publication in the *Gazzetta Ufficiale*.

The present Act, sealed with the seal of the State, shall be inserted in the Official Collection of Acts and Decrees of the Italian Republic. All persons whom it concerns are hereby required to comply with this Act and to enforce compliance therewith as an Act of the State.

Given at Rome on 20 April 1951

Certified,

Keeper of the Seals

DIRECTORATE OF THE SERVICES FOR THE CONTROL OF THE
MANUFACTURE OF AND TRADE IN DRUGS

Narcotics Bureau

No. 20400.5. AG 94/73001

Rome, 15 May 1951

SUBJECT: Regulation of the manufacture of and trade in the esters of methyl-phenyl-piperidine-carboxylic acid, their derivatives and preparations, and d-1-2-dimethylamino-4, 4-diphenyl-heptanone-5, its derivatives and preparations.

To the Prefects of the Republic	
To the President of the Council of the Valley of	AOSTA
To the Government Commissioner of the Trentino-Alto Adige Region	TRENT
To the Deputy Government Commissioner of the Trentino-Alto Adige Region	BOLZANO
To the President of the Sardini Region	CAGLIARI
To the Regional Directorate of Public Health of Sicily	PALERMO
To the Provincial Health Officers of:	
Agrigento, Caltanissetta, Catania, Enna, Messina, Palermo,	
Ragusa, Syracuse, Trapani	
To the Italian Mission	TRIESTE

Circular No. 44

The *Gazzetta Ufficiale* No. 105 of 10 May 1951 contains the text of Act No. 301 of 20 April 1951 amending Act No. 631 of 10 August 1950. Act No. 301 provides that, as from the day following the day of publication of the Act, the esters of methyl-phenyl-piperidine-carboxylic acid, their derivatives and preparations and d-1-2-dimethylamino-4, 4-diphenyl-heptanone-5, its derivatives and preparations, shall be included among the substances subject to the provisions on narcotic drugs contained in articles 150 and 151 of the Consolidated Public Health Acts, approved by Royal Decree No. 1265 of 27 July 1934.

For the purposes of the application of the new Act, the regulations to be complied with by factories manufacturing and by firms which deal in the esters of methyl-phenyl-piperidine-carboxylic acid and their derivatives and preparations, and d-1-2-dimethylamino-4, 4-diphenyl-heptanone-5 and its derivatives and preparations are given below:

PRODUCERS

Manufacturers of the esters of methyl-phenyl-piperidine-carboxylic acid and their derivatives and preparations, and of d-1-2-dimethylamino-4, 4-diphenyl-heptanone-5 and its derivatives and preparations, including proprietary preparations containing one or more of the said substances in any proportion shall be requested to transmit to the Office of the High Commissioner for Hygiene and Public Health, through the competent prefecture, a written application bearing a 32-lire stamp for the authorization prescribed by article 150 of the Consolidated Public Health Acts. The application must state:

- (a) the name and address of the firm;
- (b) the nature of the firm's activities: it should be stated whether ordinary substances or preparations, or proprietary preparations containing substances subject to the provisions on narcotic drugs are manufactured. In the latter case, the name of each proprietary preparation should be given and the authorization for the manufacture of and trade in the preparations cited;

(c) the date, and the signature of the firm's legal representative.

Applications must be accompanied by:

(1) The certificate of registration with the Chamber of Commerce, Industry and Agriculture showing that the firm is a producer of chemical drugs;

(2) The certificate of registration with the Association of Pharmaceutical Manufacturers;

(3) A stamped paper bearing a thirty-two lire stamp for the authorization order and another, also bearing a thirty-two lire stamp, for the copy.

The completed application and the attached papers are to be forwarded to the Office of the High Commissioner for Hygiene and Public Health after the customary inquiries concerning the firm's commercial probity and moral standing have been made. The report must in all cases be accompanied by a general police certificate, *to be requested officially* on behalf of the firm's legal representative, giving particulars, where applicable, of offences in respect of which an amnesty has been granted, and of sentences either suspended or remitted.

If the firm has one or more branches engaged or to be engaged in the manufacture of the substances or preparations referred to, separate applications for authorization must be made for each branch and submitted through the competent prefecture in accordance with the procedure described above.

The authorization issued by the Office of the High Commissioner entitles the firm to engage in the manufacture of the product concerned and also in the import, export, transit and wholesale trade in the product within the territory of the Republic.

If the firm is already in possession of the authorization referred to in article 150 of the Consolidated Public Health Acts, it should merely submit a statement bearing a thirty-two lire stamp to the effect that, in accordance with Act No. 301 of 20 April 1951 and the present circular, the firm has taken steps to enter the esters of methyl-phenyl-piperidine-carboxylic acid and their derivatives and preparations and d-1-2-dimethylamino-4, 4-diphenyl-heptanone-5 and its derivatives and preparations in its register of receipts and deliveries of narcotic substances, giving the names of any proprietary preparations produced containing such substances. It should also be stated whether the raw materials of such proprietary preparations are produced in the firm's laboratory or acquired from trade sources.

TRADERS

Only firms already in possession of prefectural authorization within the meaning of article 151 of the Consolidated Public Health Acts may henceforth import, export, introduce in transit or sell, within the territory of the Republic, to pharmacies open to the public or to the internal pharmacies of hospitals the substances recently included in the list of narcotic drugs or preparations thereof, including proprietary drugs.

The above provision is in conformity with the policy regarding the limitation of the number of traders adopted by the Office of the High Commissioner of Hygiene and Public Health with a view to avoiding any increase in the already considerable number of firms authorized to trade in narcotic drugs.

BOOK OF RECEIPTS AND DELIVERIES AND REGISTER OF REQUESTS Obligations of manufacturers

Manufacturers of the substances referred to above and of preparations, including proprietary preparations, containing one or more of the said substances in any proportion are required to keep a record of receipts and deliveries in the register prescribed in article 26 of Regulations No. 1086 of 11 April 1929 in the manner laid down in article 27.

Such substances and preparations may be sold or transferred to other manufacturing firms, trading firms and pharmacies open to the public or the internal pharmacies of hospitals in strict conformity with articles 34, 35 and 36 of the above-mentioned Regulations.

Obligations of traders, wholesale dealers and pharmacists

Persons authorized to engage in the wholesale trade, within the meaning of article 151 of the Consolidated Public Health Acts, and pharmacists are required to enter in the book of receipts and deliveries prescribed in article 26 of the above-mentioned Regulations acquisitions and sales of all such substances and preparations thereof; in the case of the latter, the corresponding amounts of the basic substances must be calculated and entered.

Proprietary preparations containing one or more of the substances referred to must bear on the wrapping a red label with the words "Subject to the regulations on narcotic drugs - Sold on presentation of a doctor's prescription".

Applications for authorization must be submitted by manufacturing firms not later than 30 June. Persons concerned should therefore be advised that, if no action is taken before that date, the Office of the High Commissioner will not consider any subsequent applications for authorization, and reserves the right to apply the provisions of the law.

It is requested that the greatest possible publicity should be given to the provisions of this circular in the Press and otherwise.

The Office of the High Commissioner trusts that the rules contained in this circular will be fully and strictly applied. Acknowledgment of receipt of the circular is requested.

HIGH COMMISSIONER

E/NL.1953/37

THE HIGH COMMISSIONER

In consultation with the Ministers for Home Affairs, Finance and Treasury;
Considering the urgent need to establish an inter-departmental committee representing the various Departments of State concerned with the licit and illicit traffic in narcotic drugs for the purpose of co-ordinating control over such traffic;

Having regard to:

Act No.1086 of 11 April 1929 on the prevention of the illicit trade in narcotic substances;

The International Geneva Convention of 13 July 1931;

Act No.130 of 16 January 1933 whereby the said Convention was given full effect in Italy;

The Consolidated Public Health Acts approved by Royal Decree No.1265 of 27 July 1934;

Article 3 of Act No.888 of 4 November 1950;

DECREES

An Inter-departmental Committee of Co-ordination between the Office of the High Commissioner for Hygiene and Public Health, and the Ministries of Home Affairs and Finance is hereby established for the purposes set out above.

It shall be composed of:

two representatives of the Office of the High Commissioner for Hygiene and Public Health;

two representatives of the Ministry of Home Affairs;

two representatives of the Ministry of Finance.

An official of the Office of the High Commissioner for Hygiene and Public Health of not less than grade nine shall act as Secretary.

This Decree shall be communicated to the Court of Audit for registration in accordance with the law.

Rome, 24 September 1951

FOR THE PRESIDENT OF THE COUNCIL
OF MINISTERS

HIGH COMMISSIONER

MINISTER OF HOME AFFAIRS

MINISTER OF FINANCE AND ACTING MINISTER OF THE TREASURY

Certified at the Office of the Ministry of the Treasury attached to the Office of the High Commissioner for Hygiene and Public Health.

Rome, 6 February 1952

For the Executive Director

Registered at the Court of Audit

29 February 1952

Registration No.60, File No.23

E/NL.1953/38

THE PRESIDENT OF THE COUNCIL OF MINISTERS
IN CONSULTATION WITH

THE MINISTERS OF HOME AFFAIRS, FINANCE AND THE TREASURY

Having considered the Decree of this day's date in which provision is made for the establishment of an Inter-departmental Committee of Co-ordination between the Office of the High Commissioner for Hygiene and Public Health, the Ministries of Home Affairs and Finance for the purpose of co-ordinating control over the licit and illicit traffic in narcotic drugs;

Considering that the Director of the Services for the Control of the Manufacture of and Trade in Drugs of the Office of the High Commissioner for Hygiene and Public Health must be a member of the said Committee and should preside over it;

Having regard to:

Act No.1086 of 11 April 1929 on the prevention of the illicit trade in narcotic substances;

The International Geneva Convention of 13 July 1931;

Act No.130 of 16 January 1933 whereby the said Convention was given full effect in Italy;

The Consolidated Public Health Acts approved by Royal Decree No.1265 of 27 July 1934;

Article 3 of Act 888 of 4 November 1950;

DECREES

The Director of the Services for the Control of the Manufacture of and Trade in Drugs is hereby appointed to the Inter-departmental Committee of Co-ordination between the Office of the High Commissioner for Hygiene and Public Health and the Departments of Home Affairs and Finance and shall act as its Chairman.

This Decree shall be communicated to the Court of Audit for registration in accordance with the law.

Rome, 24 September 1951

FOR THE PRESIDENT OF THE COUNCIL
OF MINISTERS

HIGH COMMISSIONER

MINISTER OF HOME AFFAIRS

MINISTER OF FINANCE AND ACTING MINISTER OF THE TREASURY

Certified at the Office of the Ministry of the Treasury attached to the Office of the High Commissioner for Hygiene and Public Health

Rome, 14 October 1952

For the Executive Director

Registered at the Court of Audit

5 November 1952

Registration No.69, File No.263

E/NL.1953/39

THE PRESIDENT OF THE COUNCIL OF MINISTERS
IN CONSULTATION WITH

THE MINISTERS OF HOME AFFAIRS, FINANCE AND THE TREASURY

Having considered the Decree of this day's date in which provision is made for the establishment of an Inter-departmental Committee of Co-ordination between the Office of the High Commissioner for Hygiene and Public Health, and the Ministries of Home Affairs and Finance for the purpose of co-ordinating control over the licit and

illicit traffic in narcotic drugs;

Considering that a representative of the Ministry of Foreign Affairs must be appointed to the Committee;

Having regard to:

Act No.1986 of 11 April 1929 on the prevention of illicit trade in narcotic substances;

The International Geneva Convention of 13 July 1931;

Act No.130 of 16 January 1933 whereby the said Convention was given full effect in Italy;

The Consolidated Public Health Acts approved by Royal Decree No.1265 of 27 July 1934;

Article 3 of Act No.888 of 4 November 1950;

DECREES

A representative of the Ministry of Foreign Affairs is hereby appointed to the Inter-departmental Committee for Co-ordination between the Office of the High Commissioner for Hygiene and Public Health and the Ministries of Home Affairs and Finance.

This Decree shall be communicated to the Court of Audit for registration in accordance with the law.

Rome, 24 September 1951

FOR THE PRESIDENT OF THE COUNCIL
OF MINISTERS

HIGH COMMISSIONER

MINISTER OF HOME AFFAIRS

MINISTER OF FINANCE AND ACTING MINISTER OF THE TREASURY

Certified at the Office of the Ministry of the Treasury attached to the Office of the High Commissioner for Hygiene and Public Health

Rome, 14 October 1952

For the Executive Director

Registered at the Court of Audit

24 December 1952

Registration No.71, File No.123

E/NL. 1953/40

THE HIGH COMMISSIONER

Having considered the Inter-departmental Decrees of this day's date appointing the Director of the Services for the Manufacture of and Trade in Drugs as a member and Chairman of the Inter-departmental Committee of Co-ordination between the Office of the High Commissioner for Hygiene and Public Health and the Ministries of Home Affairs and Finance and a representative of the Ministry of Foreign Affairs as a member of the same Committee;

Having regard to:

Act No. 1086 of 11 April 1929 on the prevention of illicit trade in narcotic substances;

The International Geneva Convention of 13 July 1931;

Act No.130 of 16 January 1933 whereby the said Convention was given full effect in Italy;

The Consolidated Public Health Acts, approved by Royal Decree No.1265 of 27 July 1934;

Article 3 of Act No.888 of 4 November 1950;

DECREES

The following are hereby appointed to the said Committee:

Dr. G.A. CARLO ANGIUS

Director of the Services for the Control and Manufacture of and Trade in Drugs of the Office of the High Commissioner for Hygiene and Public Health, Chairman

Dr. VITTORIO LAVISON

Of the Office of International Organizations of the Ministry of Foreign Affairs

Rome, 24 September 1951

HIGH COMMISSIONER

Certified at the Office of the Ministry of the Treasury attached to the Office of the High Commissioner for Hygiene and Public Health

Rome, 14 October 1952

For the Executive Director

Registered at the Court of Audit

24 December 1952

Registration No.71, File No.124

E/NL.1953/41

THE HIGH COMMISSIONER

Having considered his Decree of this day's date in which provision is made for the establishment of an Inter-departmental Committee of Co-ordination between the Office of the High Commissioner of Hygiene and Public Health and the Ministries of Home Affairs and Finance for the purpose of co-ordinating control over the licit and illicit traffic in narcotic drugs;

Having regard to:

Act No.1086 of 11 April 1929 on the prevention of illicit trade in narcotic substances;

The International Geneva Convention of 13 July 1931;

Act No.130 of 16 January 1933 whereby the said Convention was given full effect in Italy;

The Consolidated Public Health Acts, approved by Royal Decree No.1265 of 27 July 1934;
Article 3 of Act No.888 of 4 November 1950;

DECREES

The following are hereby appointed to the said Committee:

Dr. ROBERTO SCANDALIATO,	Chief of the Office of the High Commissioner for Hygiene and Public Health;
Dr. GABRIELE TANCREDI,	Head of the Bureau of Narcotics of the Office of the High Commissioner for Hygiene and Public Health;
Dr. GIUSEPPE DOSI,	Head of the Interpol Office
Dr. CALOGERO MAROCCO,	Chief Commissioner for Public Health attached to the Ministry of Home Affairs;
Dr. RAFFAELE CIRINCIONE,	Chief of Division of the Ministry of Finance and
Lt. Colonel CESARE PATRASSI,	H.Q. of the Fiscal Police.

Dr. DANIELE MAGGI, Provincial medical officer (first class) will act as Secretary.

This Decree shall be communicated to the Court of Audit for registration.

Rome, 24 September 1951

FOR THE PRESIDENT OF THE COUNCIL OF MINISTERS

HIGH COMMISSIONER

Registered at the Court of Audit
29 February 1952
Registration No.60, File No.22

Certified at the Office of the Ministry of the Treasury attached to the Office of the High Commissioner for Hygiene and Public Health

Rome, 6 February 1952

For the Executive Director