



UNITED NATIONS

E/NL 1957/56

15 October 1957

Original: FRENCH

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

FRANCE

Communicated by the Government of France

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 text.

ORDER RESTRICTING DELIVERIES AND STOCKS OF

NARCOTIC DRUGS

The Secretary of State for Public Health and Population,

having considered the Public Health Code, especially articles L626 to L630, R5190 to R5195;

having considered the Act of 6 April 1933 ratifying the Convention signed at Geneva on 13 July 1931 for the limitation of the manufacture and distribution of narcotic drugs, and also the Decree of 30 June 1933;

having considered the opinion of the Inter-Ministerial Committee on Narcotic Drugs dated 4 April 1957;

on the proposal of the Chief of the Central Pharmaceutical Office

ORDERS AS FOLLOWS:

Article 1. -

The total quantity of products subject to the provisions of the Public Health Code (part 2) volume V, title III part III, paragraph 4, delivered by manufacturers authorized, under the provisions of article R5190 of the above Code, to extract alkaloids of opium, opium poppy and coca leaf, to synthesize 1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester [Pethidine]¹⁾ and to manufacture their salts and derivatives shall not in 1957 exceed-

1) Note by the Secretariat: The words in square brackets have been inserted by the Secretariat. Proposed or recommended international non-proprietary names of drugs are underlined.

NAME		QUANTITIES IN TERMS OF
I.	Total for all firms authorized to extract alkaloids from opium and opium poppy:	Kg.
	Morphine and its salts	150 Basic anhydrous morphine
	Diacetylmorphine and its salts	10 Diacetylmorphine
	Dihydrooxycodone / <u>Oxycodone</u> / and its salts	50 Dihydrooxycodone
	Thebaine (for conversion)	150 Thebaine
	Dihydrocodeinone / <u>Hydrocodone</u> / and its salts	1 Dihydrocodeinone
	Dihydromorphinone / <u>Hydromorphone</u> / and its salts	1 Dihydromorphinone
	Benzylmorphine and its salts	1 Benzylmorphine
	Methylmorphine and its salts	7,000 Methylmorphine
	Ethylmorphine and its salts	2,250 Ethylmorphine
	<u>Pholcodine</u> and its salts.	350 <u>Pholcodine</u>
II.	Firms producing alkaloids from coca leaf:	
	Cocaine and its salts	125 Basic cocaine
III.	<u>Pethidine</u> and its salts	400 Basic <u>pethidine</u>

Article 2. -

Manufacturers referred to in Article 1 may hold stocks as reserve from which they can make their deliveries. The stocks of finished products shall not exceed-

NAME		QUANTITIES IN TERMS OF
I.	Total for all firms at present extracting alkaloids from opium and opium poppy:	Kg.
	Morphine and its salts	500 Basic anhydrous morphine
	Diacetylmorphine and its salts	20 Diacetylmorphine
	Dihydrooxycodone and its salts	25 Dihydrooxycodone
	Thebaine (for conversion).	150 Thebaine
	Dihydrocodeinone and its salts.	5 Dihydrocodeinone
	Dihydromorphinone and its salts	5 Dihydromorphinone
	Dihydrocodeine and its salts.	5 Basic Dihydrocodeine
	Benzylmorphine and its salts	2 Benzylmorphine
	Methylmorphine and its salts	1,500 Methylmorphine

NAME		QUANTITIES IN TERMS OF
I.	Total for all firms at present extracting alkaloids from opium and opium poppy:	Kg.
	Ethylmorphine and its salts	750 Ethylmorphine
	<u>Pholcodine</u> and its salts	200 <u>Pholcodine</u>
II.	Total for all firms at present extracting alkaloids from coca leaf:	
	Cocaine and its salts	125 Basic cocaine
III.	<u>Pethidine</u> and its salts	400 Basic <u>pethidine</u>

Article 3. -

Manufacturers authorized to treat opium in order to extract alkaloids therefrom shall report to the Narcotic Drugs Bureau the results of the Harrison test for each consignment of opium purchased.

Manufacturers authorized to extract alkaloids from opium poppy, coca leaf or raw cocaine shall report the narcotic alkaloid content of each consignment of raw materials purchased and, if required to do so by the Narcotic Drugs Bureau, supply it with samples for assay.

Article 4. -

Firms authorized to treat raw opium, opium poppy (capsules, stalks etc.) and coca leaves in order to extract alkaloids or manufacture galenical preparations therefrom shall send to the Central Pharmaceutical Office, Narcotic Drugs Bureau -

At the end of each month -

A statement containing the following particulars relating to raw opium, opium poppy plant (capsules, stalks, etc.) coca leaf and raw cocaine:

- (i) stock in hand at end of previous month;
- (ii) quantities received at factory;
- (iii) quantities used -
 - (a) for extraction of alkaloids of opium or coca leaf;
 - (b) for sale (name and address of buyers and quantities delivered must be stated in each case);
- (iv) stock in hand at end of month.

At the end of each quarter -

A statement on the manufacture of galenical preparations, containing the following particulars:

- (i) quantities of raw materials in stock at end of previous quarter;
- (ii) quantities received at factory;

- (iii) quantities used for manufacture (separately for each raw material), specifying average active-principle content of each batch;
- (iv) quantities of each galenical preparation manufactured;
- (v) quantities of each galenical preparation -
 - (a) used for manufacture of other preparations, and quantities of such preparations produced;
 - (b) quantities of each galenical preparation, or of preparations containing it, sold during quarter;
- (vi) in respect of each raw material and each preparation: stocks in hand at end of quarter.

Article 5. -

At the end of each month manufacturers to whom article 1 applies shall send to the Central Pharmaceutical Office (Narcotic Drugs Bureau) the following statements compiled in terms of basic anhydrous morphine, basic cocaine, pure dihydrooxycodine, pure dihydrocodeine, pure dihydromorphine, and hydrochloride of -1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester:

- (i) A statement showing -
 - (a) the quantities of morphine, natural codeine and thebaine extracted, and the quantities of cocaine, dihydrooxycodine, pure dihydrocodeine, dihydromorphine, and 1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester manufactured;
 - (b) the quantities of morphine used in manufacture (salts and derivatives);
 - (c) the quantities of salts or derivatives manufactured. The quantities used by manufacturers of alkaloids in the preparation of solutions or dilutions or of medicinal products shall be shown on the statement.
- (ii) A statement of deliveries of the products referred to in article 1 made during the month, including the names and addresses of the buyers and the name and quantity of the product delivered to each;
- (iii) A statement showing the quantities of each finished product remaining in stock.
- (iv) A request for authorization to manufacture, where appropriate -
 - (a) the quantities required to replace those delivered during the month;
 - (b) the additional quantities required to raise the manufacture's stocks to the permitted level.

Article 6. -

The products of a conversion carried out to order shall be included in the stocks and deliveries of the firm carrying out the conversion.

Article 7. -

Where the deliveries to which article 1 applies are to be exceeded, the Central Pharmaceutical Office (Narcotic Drugs Bureau) shall, when the total quantity delivered is about to reach the figures laid down in that article, notify the firm that with effect from the date of the notice the firm is required to report each delivery on the day on which it is made.

When the aforesaid maximum figures are reached, the Narcotic Drugs Bureau shall notify the firm that no further delivery may be made.

In case of emergency, however, a request for permission to deliver may be submitted to the Bureau, which shall issue a delivery permit for each consignment so authorized.

Article 8. -

Firms authorized to manufacture preparations containing more than 20 per cent of morphine derived directly from raw or medicinal opium or from poppy plant (capsules, stalks, etc.) shall send in to the Central Pharmaceutical Office (Narcotic Drugs Bureau) at the end of each quarter a statement showing-

- (i) the quantity of raw or medicinal opium or of the opium poppy (capsules, stalks, etc.) used in the manufacture of the said preparations;
- (ii) the date of manufacture;
- (iii) in respect of each batch of opium or of poppy plant treated, the quantities of preparations obtained and the date of completion of manufacture;
- (iv) the quantity in process of manufacture into pharmaceutical preparations;
- (v) the quantities sold during the quarter, in their natural state or in the form of pharmaceutical preparations;
- (vi) the stock of finished products in hand or ready for sale.

This statement, which contains the same particulars as the statement required by article R5195 of the Public Health Code (part 2), shall replace the said statement, but only in respect of those preparations to which it applies.

Article 9. -

The Chief of the Central Pharmaceutical Office shall give effect to this Order.

Done at Paris, 15 April 1957

(signed) MAROSELLI