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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

BRAZIL

Communicated by the Government of Brazil

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.

Ministry of Health

REGULATION No. 3 OF 2 APRIL 1962

The Director of the National Medical and Pharmaceutical Control Service, pursuant to the provisions of article 29, section XI, of the By-Laws of the National Medical and Pharmaceutical Control Service as approved by Decree No. 41,904,

Considering that the consumption of psychotropic medicinal substances without a doctor's prescription is becoming a practice which entails grave risks to public health;

Considering that the stipulation in the licences issued by the National Medical and Pharmaceutical Control Service that such drugs must only be sold "against a medical prescription" is not being complied with in a satisfactory manner;

Considering the urgent need for strict and effective control over the consumption of certain psychotropic substances or proprietary drugs, the indiscriminate use of which gives rise to social evils;

HEREBY DECIDES:

Article 1

Laboratories, pharmacies, druggist's shops, drug wholesalers, hospitals and similar establishments shall be obliged to record in an appropriate register - which shall be opened, endorsed on each page and closed by the competent Federal, State or Territorial health authority - all the pharmaceutical substances or proprietary drugs specified in article 6 of this Regulation which they obtain.

Article 2

The pharmacists in charge of the above-mentioned establishments shall be responsible for ensuring that all medical prescriptions including the pharmaceutical substances or proprietary drugs covered by that article are recorded in the said register; the prescriptions in question shall be kept for subsequent verification and approval by the supervisory authority.

Article 3

Laboratories manufacturing proprietary drugs of the kind specified in article 6 shall place the following printed notice, in addition to the legal restriction "To be sold solely against a medical prescription", in prominent characters on the packaging and labels of such drugs: "This product to be used under a doctor's orders and subject to his supervision, since it contains substances having a psychotropic effect". The same wording will automatically appear on the licences issued in connexion with these proprietary drugs.

Sole paragraph A period of sixty days shall be allowed to enable all licences already issued to be altered to conform to this Regulation.

Article 4

Laboratories shall limit the total quantity of the samples which they distribute solely to doctors to 5 per cent of their factory output of the substances referred to in article 6. The words mentioned in article 3 shall likewise be printed on the packaging and labels of such samples.

Article 5

Whenever it deems it necessary to do so, the Medical and Pharmaceutical Control Service shall bring the list of the pharmaceutical substances covered by this Regulation up to date by including others; it shall be responsible for any additions and deletions.

Article 6

The following are the substances covered by the provisions of this Regulation:

(a) hypnotics and anti-spasmodics;

(b) substances having a stimulating action based on sympathicomimetic amines or substances of a similar chemical structure, i.e. those which produce excitation of the central nervous system;

(c) hallucinogenic substances such as Mescaline and LSD. The characteristics of the above-mentioned pharmaceutical substances and proprietary drugs shall be determined in accordance with the particulars entered on the relevant licence issued by the National Medical and Pharmaceutical Control Service.

Article 7

To enable the supervisory authority to keep a check on consumption, pharmaceutical laboratories shall prepare special control cards, confirming sales made and any rebate granted to the establishment purchasing them for proprietary drugs containing the substances enumerated in article 6; these cards shall be sent to the supervisory authority before the fifth day of each month, either direct or through the laboratory's professional organization. Commercial concerns shall also send to that authority, before the fifth day of each month, a statement of all goods covered by this Regulation which have been sold during the previous month; this may be done either direct or through the appropriate professional organization.

Article 8

Pharmaceutical substances or proprietary drugs acting as tranquillizers, ataractics or mental stimulants, other than those specified in article 6, shall be exempt from the requirements set out in articles 1, 2, 6 and 7 of this Regulation but shall comply with the provisions of articles 3, 4 and 5.

Article 9

Any infringement of the provisions of this Regulation shall be punished by fines levied in accordance with existing legislation; these fines shall be increased in the case of a second or subsequent offence.

Paragraph 1. After a third such infringement, and in addition to the fines provided for in this article, the supervisory authority may order the temporary closure of the establishment for thirty days; such action shall be reported immediately to the Federal Pharmaceutical Council, to enable it to take the necessary measures with regard to the pharmacist concerned on the ground that he has repeatedly committed a serious offence.

Paragraph 2. A further infringement shall render the establishment concerned liable to the penalties provided for by law.

Article 10

This Regulation shall come into force on the date of its publication. Regulation No. 3 of 28 April 1951 is hereby abrogated.

FERNANDO LUZ FILHO
Director,
National Medical and Pharmaceutical Control Service

Rio de Janeiro, 2 April 1962.