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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

BOLIVIA

Communicated by the Government of Bolivia

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

HEALTH CODE OF THE REPUBLIC OF BOLIVIA, 1958

CHAPTER II

CONTROL OF MEDICINAL, BIOLOGICAL, CHEMICAL AND PHARMACEUTICAL PRODUCTS, PROPRIETARY MEDICINES AND NARCOTIC DRUGS

Article 123

The National Health Service shall propose and the Ministry of Public Health shall issue regulations laying down conditions and detailed rules or standards for the production, manufacture, storage, importation, packaging, analysis, registration, distribution and sale of medicinal, biological, chemical and pharmaceutical products, proprietary medicines and narcotic drugs, and also for their quality, purity, composition and other physical, chemical and biological characteristics. It shall likewise establish the administrative procedures for authorizing or rejecting such products. For the purposes of this provision, so-called beauty products and cosmetics, medical appliances, contraceptives and biological media for clinical diagnosis, products for preventing or curing animal diseases and, in general, all products which are sold in pharmacies or similar establishments and are used in any manner whatsoever for the health of individuals or the community shall be treated as such products.

Article 124

The National Health Service shall be responsible through the District Services and Health Centres for the application of the regulations referred to in article 123. It shall be empowered:

(a) to issue permits for the importation or manufacture of any proprietary medicine sold in Bolivia after it has been analysed and the appropriate entry made in the register to be kept for this purpose;

(b) to control, restrict or prohibit the advertising or publication of announcements extolling the preventive or curative properties of such products when they do not conform to the standard approved by the National Health Service at the time of registration;

(c) to prohibit the importation, manufacture, packaging or sale of any proprietary medicine, the formula of which is incorrect and is not in conformity with the contents, or where the components are chemically or therapeutically incompatible, or where any of the relevant regulations are infringed;

(d) to inspect pharmacies, druggists' or apothecaries' shops, pharmaceutical laboratories, factories for medicinal products or any similar establishments;

(e) to take such steps as it deems appropriate, within the limitations of this Code, for the effective exercise of control over such products.

Article 125

The products referred to in this Chapter, whether domestic or foreign, shall be liable to Customs duties and the fees for annual registration specified in the regulations proposed by the National Health Service and issued by the Ministry of Health.

Article 126

Any of the products referred to which have been declared by the National Health Service to be contaminated, adulterated or falsified or any such products not authorized in their country of origin may not be imported, stored, distributed, sold or used in any manner whatsoever.

Article 127

The selling price to the public, the name and address of the manufacturer, the registration number and the date on which their potency expires shall be printed legibly in Spanish in such a position as to be clearly visible on the packaging of the domestic and foreign products referred to in this Chapter as subject to the regulations.

Article 128

Bolivian Customs offices may not release such products, their labels or packaging unless the corresponding invoices are signed by a competent official of the National Health Service.

Article 129

The reports and other official documents containing the findings of the analysis and examination of the products referred to in this Chapter may not be used in commercial advertising without the permission of the National Health Service.

Article 130

The agricultural or industrial production, manufacture, import or export, carriage or distribution in any manner whatsoever, trade, purchase, possession, medical prescription, use, consumption and, in general, any act relating to the trade in or supply of narcotic drugs, their derivatives or any product deemed to be such, shall be governed by the provisions of the relevant international treaties and conventions to which Bolivia is a party, the provisions of this Code and all other laws in force.

Article 131

Detailed regulations shall be proposed by the National Health Service and issued by the Ministry of Health for all matters connected with the trade in narcotic drugs throughout Bolivian territory or intended for other countries in accordance with the international obligations undertaken by the Government, and for all the other operations referred to in article 128.

Article 132

Only duly registered physicians, veterinary surgeons and dentists may prescribe narcotic drugs. They must specify in each case what use they intend to make of them and must supply any other information specified in the relevant Regulations. Pharmacists may not dispense prescriptions unless these are made out on official prescription forms in accordance with the specifications laid down in the relevant regulation.

Article 133

Except as otherwise provided in articles 130, 131 and 132, the National Health Service shall be responsible for all matters pertaining to the control of narcotic drugs, their derivatives and similar products.

Article 134

The National Health Service shall propose and the Ministry of Health shall issue regulations governing all matters pertaining to registration certificates for narcotic drugs and the fees charged for them.

Article 135

To facilitate the performance of the duties, functions and obligations laid down in this Act connected with the control of the products referred to in this Chapter, the owners or managers of undertakings or establishments for the importation, manufacture, packaging, storage, distribution or sale of such products must allow properly accredited officials of the National Health Service free access to their premises, and permit them to inspect installations, machinery, workshops, equipment, utensils, vehicles and stocks. They must also furnish the necessary samples, in accordance with the law and regulations in force. Samples shall be cleared by the Customs against a receipt, sealed counter-samples being left with the Customs. Moreover, officials of the National Health Service may withdraw from the Customs any samples they deem it necessary to examine.