E/NL 1953/92-93
2 July 1953

UNITED NATIONS

# 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

# POLAND

COMMUNICATED BY THE GOVERNMENT OF

POLAND

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*

Original: Polish

E/NL. 1953/92

# *Act of 8 January 1951*
# *on Pharmaceutical Products, Narcotic Drugs and Medical Appliances*

## *General Provisions*

### *Article 1*

Pharmaceutical products are either pharmaceutical substances or medicines.

### *Article 2*

For the purposes of this Act "pharmaceutical substances" means substances and preparations and products thereof manufactured or converted for the purpose of compounding medicines in pharmacies.

### *Article 3*

1. For the purposes of this Act "medicines" means pharmaceutical substances and preparations and products thereof prepared in a form suitable for direct use in the treatment of man or animals or for the prevention or diagnosis of disease.
2. Medicines are either prescribed medicines or medical preparations.
3. A prescribed medicine is a medicine compounded for a particular person according to a single prescription; and any other medicine is a medical preparation.

### *Article 4*

1. For the purposes of this Act "medical appliances" means materials for dressings and surgical sutures of catgut or thread.
2. The Minister of Health may, by order made in agreement with the chairman of the National Economic Planning Commission, declare other appliances of use in protecting health to be medical appliances.

### *Article 5*

1. For the purposes of this Act "narcotic drugs" are -
   (a) Raw opium
   (b) Medicinal opium
   (c) Smoking opium and its residues
   (d) Hashish
   (e) Coca leaf (*Folium coca*)
   (f) Indian hemp (*Herba cannabis indicae*) and products and preparations thereof
   (g) Ethyl ether and preparations thereof
   (h) Morphine, its esters and other pentavalent nitrogen derivatives
   (i) Cocaine
   (j) Heroin (diacetylmorphine)
   (k) Dicodide (dihydrocodeinone)
   (l) Dihydrooxycodeinone
   (m) Dihydromorphine
   (n) Dihydromorphinone
   (o) Tropacocaine
   (p) Ecgonine
   (q) Benzoylecgonine

(r) Methylecgonine
(s) Acetyldihydrocodeinone, its salts and preparations thereof (acedicone, acetylodemethyldihydrothebainone)

2. On the authority of scientific research the Minister of Health may by order classify other substances and products as narcotic drugs.

3. Narcotic drugs which are pharmaceutical products shall be governed both by the provisions relating to narcotic drugs and by those relating to pharmaceutical products

*Article 6*

A pharmaceutical product or medical appliance shall be deemed to be spoiled if as a result of any change in its normal composition or character due to natural causes such as lapse of time, temperature, moisture, light, bacteria or contamination, it fails to satisfy the prescribed standards of quality.

*Article 7*

A pharmaceutical product or medical appliance shall be deemed to be an imitation if it is so presented as to appear to be some other product than it is in reality but has only the appearance and not the character or composition of the other product.

*Article 8*

A pharmaceutical product or medical appliance shall be deemed to be adulterated if its ordinary composition has been altered by addition or subtraction or combination with another product so that its power to protect health is decreased or it does not satisfy the prescribed standards of quality.

*Manufacture and marketing of pharmaceutical products, medical appliances and narcotic drugs*

*Article 9*

1. It shall be lawful to manufacture and market only those pharmaceutical substances and medical preparations which are included in an official list of medicines or other schedule drawn up by the Minister of Health and those pharmaceutical substances and veterinary medical preparations included in the schedule drawn up by the Ministers of Health and of Agriculture and Agrarian Reform.

2. Provisions concerning the official list of medicines and the other schedules referred to in paragraph 1 shall be laid down by the Minister of Health in an Order made in agreement with the chairman of the National Economic Planning Commission and, in respect of schedules of pharmaceutical substances and veterinary medical preparations, made jointly with the Minister of Agriculture and Agrarian Reform

3. Only the pharmaceutical substances and medical preparations referred to in paragraph 1 may be used for the manufacture of prescribed medicines.

*Article 10*

Prescribed medicines may be manufactured only in pharmacies or, for veterinary use, in veterinary establishments.

*Article 11*

1. Pharmaceutical substances, medical preparations and medical appliances may,

subject to the provisions of paragraph 2, be manufactured only under a licence issued by the Minister of Health or by a person acting under his authority.
2. The Minister of Health may by order determine the pharmaceutical substances and medical appliances which may be manufactured without a licence.
3. The Minister of Agriculture and Agrarian Reform, acting in agreement with the Minister of Health, shall have with respect to pharmaceutical substances and medical preparations intended exclusively for veterinary use the powers of the Minister of Health described in paragraphs 1 and 2.
4. The provisions of paragraphs 1 and 2 shall not apply to a pharmaceutical substance, medical preparation or medical appliance manufactured by an establishment under the Minister of National Defence or of Social Security and intended for the military or social security medical services.

*Article 12*

1. Wholesale trade in pharmaceutical products and medical appliances may be carried on only by pharmaceutical wholesale or warehousing establishments or in open pharmacies under licences issued by the Minister of Health or by a person acting under his authority, and in pharmaceutical products intended for veterinary use, and by other establishments, only under licences issued by the Minister of Agriculture and Agrarian Reform acting in agreement with the Minister of Health.
2. The provisions of paragraph 1 shall not apply to pharmaceutical wholesale or warehousing establishments or pharmacies under the Ministers of National Defence and of Social Security.

*Article 13*

The Minister of Health shall, by order made in agreement with the chairman of the National Economic Planning Commission, and in respect of pharmaceutical products intended for veterinary use also in agreement with the Minister of Agriculture and Agrarian Reform, determine the manner in which the licences referred to in articles 11 and 12 shall be issued.

*Article 14*

1. Retail trade in pharmaceutical products and medical appliances may, subject to the provisions of paragraphs 2 and 3*, be carried on only in pharmacies.
2. The Minister of Health shall determine the pharmaceutical products and medical appliances which may be marketed in other places of public sale and, by agreement with the Minister of Internal Trade, the conditions under which trade may be carried on in such places.
3. Retail trade may also be carried on through national veterinary establishments in pharmaceutical products intended exclusively for veterinary use.

*Article 15*

1. Every establishment manufacturing or marketing pharmaceutical products shall have a testing laboratory to test the uniformity and quality of those products.
2. The Minister of Health may exempt a particular establishment or class of establishments from the duty of conducting a testing laboratory.

* Original

*Article 16*

1. The Minister of Health shall by order determine with respect to pharmaceutical products and medical articles -
   (a) requirements for storage, quality and testing methods,
   (b) methods of marking,
   (c) requirements which must be fulfilled by places of manufacture, warehousing and wholesale trade, and in particular the number and equipment of testing laboratories,
   (d) qualifications of staff employed in manufacture and wholesale trade,
   (e) warehousing and marketing methods.
2. The Minister of Health shall make the orders referred to in paragraph 1, in so far as they relate to pharmaceutical products intended for veterinary use, by agreement with the Minister of Agriculture and Agrarian Reform, and the orders referred to in paragraph 1 (c-d) by agreement with the chairman of the National Economic Planning Commission.
3. The Minister of Health may attach to the licences referred to in articles 11 and 12 special conditions not provided for in orders made under paragraph 1.

*Article 17*

1. Directors of manufacture shall be liable for -
   (a) manufacture of pharmaceutical products or medical appliances according to law,
   (b) their uniformity,
   (c) their quality during their period of efficacy if their date of efficacy is marked on the package or, if not, for three years, and
   (d) their warehousing in the factory according to law.
2. Directors of pharmaceutical wholesale or warehousing establishments shall be liable for -
   (a) warehousing of pharmaceutical products or medical appliances in the wholesale establishment according to law,
   (b) their uniformity and quality, if marketed in packing provided by the wholesale establishment, and
   (c) marketing them according to their date of efficacy.
3. Directors of pharmacies shall be liable for -
   (a) manufacture according to law of prescribed medicines and the quality of the pharmaceutical substances used therefor,
   (b) the uniformity and quality of pharmaceutical products or medical appliances marketed in packing provided by the pharmacy,
   (c) marketing them according to their date of efficacy, and
   (d) their storage and issue from the pharmacy according to law.

*Article 18*

1. The manufacture, conversion, transport, export, internal transport, transit, warehousing and marketing of narcotic drugs shall be lawful only for medical, scientific or commercial purposes under a licence laying down conditions for their manufacture, transport, transit, warehousing and marketing. Licences for the import, export and transit of narcotic drugs shall be issued by the Minister of Foreign Trade in agreement with the Minister of Health. Other licences relating to narcotic drugs shall be issued by the Minister of Health in agreement, so far as they permit the manufacture or conversion of ethyl ether, with the Minister of Agricultural and Consumer Industries.
2. No licence shall be required for the conversion or marketing of narcotic drugs

in pharmacies for medical purposes.
3. The Minister of Health shall regulate by order the manufacture, internal transport, transit, warehousing and marketing of narcotic drugs.

*Article 19*

1. The provisions of this Act shall apply to imported pharmaceutical products, narcotic drugs and medical articles.
2. Directors of importing enterprises shall be liable for -
   (a) the uniformity of pharmaceutical products and medical appliances,
   (b) their quality during their period of efficacy, if the date of efficacy is marked on the package or, if not, their quality at the time of despatch,
   (c) their warehousing in the establishment according to law.
3. The import of pharmaceutical products, narcotic drugs and medical appliances shall, where this Act makes no provision to the contrary, be governed by the ordinary law relating to the import of goods.
4. The import by a person of a medical preparation for his own use shall be lawful only by leave of the Minister of Health or of a person acting under his authority, and for veterinary use only by leave of the Minister of Agriculture and Agrarian Reform or of a person acting under his authority.

*Control*

*Article 20*

1. General control over the manufacture, quality, warehousing and marketing of pharmaceutical products, narcotic drugs and medical appliances shall be exercised by the Minister of Health, in agreement, so far as pharmaceutical products are intended for veterinary use, with the Minister of Agriculture and Agrarian Reform. Direct State control shall be exercised by presidents of provincial people's councils, who shall supervise conditions in manufacturing, warehousing and marketing establishments.
2. State control over pharmaceutical products, narcotic drugs and medical articles manufactured, warehoused or marketed by establishments under the Ministers of National Defence and of Social Security shall be exercised by those Ministers or by persons acting under their authority.

*Article 21*

1. State control authorities may enter on all premises where pharmaceutical products, narcotic drugs or medical appliances are manufactured, warehoused or marketed and take free samples for test.
2. Pharmaceutical products, narcotic drugs and medical appliances which have been or are suspected of being spoiled, adulterated or imitated, and narcotic drugs in unlawful possession, and substances and articles suspected of containing narcotic drugs, shall be liable to confiscation by the State control authority.

*Article 22*

The Minister exercising the control referred to in article 20 may instruct recognized experts or scientific research institutes under his jurisdiction to exercise expert control over the manufacture of pharmaceutical products, narcotic drugs and medical articles.

*Article 23*

1. Regulations governing control over the manufacture, warehousing and marketing of

pharmaceutical products, narcotic drugs and medical appliances and the conduct of control authorities shall be issued by the Minister of Health by order made with the consent of the President of the Council of Ministers in agreement with the chairman of the National Economic Planning Commission and, so far as they relate to pharmaceutical products intended for veterinary use, also with the Minister of Agriculture and Agrarian Reform.
2. Regulations governing the matters referred to in paragraph 1 and affecting establishments under the Ministers of National Defence and Social Security shall be issued by those Ministers.

*Article 24*

1. Pharmaceutical products, narcotic drugs and medical appliances shall be tested by the control authority or, on its instructions, by scientific research institutes designated by the Minister of Health.
2. The Minister of Health shall prescribe by order the methods of carrying out and, in agreement with the Minister of Finance, of payment for the tests referred to in paragraph 1.

*Article 25*

1. A person, being neither a manufacturer nor an importer, from whom samples are taken under article 21, paragraph 1 may require the actual manufacturer or importer to restore to him an amount of the pharmaceutical or narcotic product or medical appliance equal to the sample taken or to pay him its wholesale price.
2. The manufacturer or importer shall restore the exact amount of the sample taken or pay its price within two weeks of the date of receipt of the claim supported by official evidence of the taking of the sample.

*Penal provisions*

*Article 26*

Any person imitating or adulterating a pharmaceutical product or medical appliance, or marketing an imitated, adulterated or spoiled pharmaceutical product or medical appliance, or manufacturing, warehousing or marketing a pharmaceutical product or medical appliance in breach of any regulation made under article 16, paragraph 1 or of a condition attached to a licence under article 11 or 12 shall be liable to a term of imprisonment not exceeding three years and to a fine.

*Article 27*

Any person manufacturing or marketing a pharmaceutical product or medical appliance without a licence or in breach of a provision of article 9 shall be liable to arrest for a term not exceeding six months or to a fine not exceeding 9,000 złotys or to both.

*Article 28*

Any person who in any way announces or advertises a pharmaceutical product by means of medical information capable of misleading shall be liable to arrest for a term not exceeding three months or to a fine not exceeding 4,500 złotys or to both.

*Article 29*

Any person manufacturing, converting, importing, exporting, transporting,

warehousing or marketing a narcotic drug without a licence or in breach of a condition of a licence shall be liable to imprisonment for a term not exceeding five years and to a fine.

*Article 30*

Any person using a narcotic drug without a doctor's prescription in the company of another person shall be liable to arrest for a term not exceeding one year or to a fine or to both.

*Article 31*

In the case of a conviction of an offence under articles 26, 27, 29 or 30 an order may be made for the forfeiture of the pharmaceutical product, narcotic drug or medical appliance the subject of the offence and of the implements and apparatus used or intended to be used for committing the offence.

*Article 32*

Any person contravening a regulation made under article 18, paragraph 3 shall be liable to arrest for a period not exceeding three months or to a fine not exceeding 4,500 złotys or to both.

*Article 33*

Any person obstructing a control authority in the execution of its official functions shall be liable to arrest for a term not exceeding three months or to a fine not exceeding 4,500 złotys or to both.

*Final Provisions*

*Article 34*

1. All previous provisions concerning the matters governed by this Order are hereby repealed, and in particular -
   (a) article 13 of the Act of 15 June 1939 on the public health services (Dz.U.R.P., No.54, item 342),
   (b) the Act of 22 June 1923 concerning narcotic substances and preparations (Dz.U.R.P., No.72, item 559), and
   (c) articles 11 and 18 of the Order of the President of the Republic of 22 August 1927 on the prevention of epizootic disease (Dz.U.R.P., No.77, item 673), as hitherto amended.
2. Until the orders provided for in this Act are made, all orders and decrees made under the provisions referred to in paragraph 1 shall, in so far as they are not contrary to this Order, remain in force.

*Article 36*

The President of the Council of Ministers and the Ministers of Health, National Defence, Social Security, Agriculture and Agrarian Reform, Foreign Trade and Justice shall give effect to this Order.

*Article 37*

This Act shall come into force on the date of its promulgation.

President of the Republic
President of the Council of Ministers
Minister of Health
Minister of National Defence
Minister of Social Security
Minister of Agriculture and Agrarian Reform
Minister of Foreign Trade
Minister of Justice

E/NL.1953/93

*Order of the Minister of Health of 14 May 1951 declaring certain substances to be narcotic drugs*

In pursuance of article 5, paragraph 2, of the Act of 8 January 1951 on Pharmaceutical Products, Narcotic Drugs and Medical Appliances (Dz.U.R.P., No. 1, item 4), it is hereby ordered as follows:

*Article 1.* The following substances are hereby declared to be narcotic drugs:

(a) Tropacocaine and its salts
(b) Morphine-N-oxide (genomorphine) and its derivatives
(c) Dihydrodesoxymorphine and its salts
(d) Methyldihydromorphinone and its salts (metopon)
(e) Thebaine and its salts
(f) 1-phenyl, 2-aminipropane and its salts (psychedirne, benzedrine, amphetamine)
(g) 1-phenyl, 2-methylaminopropane and its salts (pervitin, isophen)
(h) Ethyl ester of 1-methyl, 4-phenylpiperidine, 4-carboxylic acid and its salts (dolantine, demerol, pethidine)
(i) 1-piperidine, 3.3-diphenyl-hexanone and its salts (hexalgon)
(j) 6-dimethylamino, 4.4-diphenyl-heptanone (3) and its salts (amidone, dolamid, mecodin)

*Article 2.* This order shall come into force on the day of its promulgation.

*Minister of Health*