Norwegian Act of 20 June 1964, No 5
Relating to Medicines etc.

PART I

§ 1
This Act applies to medicines and certain other substances for medicinal use.

§ 2
Within the meaning of this Act, the term “medicines” is defined as substances, drugs and preparations intended for or used in the prevention, treatment or alleviation of human or animal illness, or pain, or for internal or external use in the diagnosis of illness. The Crown* issues regulations describing in detail what shall be defined as medicines. These regulations may also stipulate that certain substances, drugs or preparations always shall be defined as medicines irrespective of whether they may also be used for other purposes, and further, that certain substances, drugs or preparations falling within the definition above, nevertheless shall not be deemed a medicine.

The Ministry* shall in cases of doubt decide whether any item is to be defined as medicine within the meaning of this Act and the regulations.

§ 3
(Repealed by Act of 3 June, 1977, No 53)

PART II
The manufacture of medicines (pharmacy production excluded).

§ 4
The Crown may by regulation limit the commercial production of certain medicines to pharmacies only. In accordance with the provisions of these regulations, the Ministry may under specified conditions

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*The Directorate of Health
All further references to “the Crown” or “the Ministry” apply to the Directorate of Health except in § 19 where “the Ministry” refers to the Ministry of Health and Social Affairs.
make exemption from this paragraph and grant special permission for others to produce such medicines.

Unless otherwise stipulated by this Act, any person or persons wishing to commercially produce medicines outside the pharmacies must be licensed to do so by the relevant Ministry which is empowered to stipulate specific conditions for such a licence.

The production shall be supervised by a responsible person approved by the Ministry. This person shall have the same education and practical experience as is required for a pharmacist's licence or otherwise prove that he has the necessary professional training.

The Ministry is empowered to issue detailed regulations concerning the production of medicines outside the pharmacies and to require the records and information concerning the business that are considered necessary to exercise supervision and control.

§ 5
Permission granted under § 4 may be revoked by the Ministry:

1. When the manufacture is not commenced, or ceases and is not resumed within a time limit determined by the Ministry.
2. When the approved responsible person dies or leaves his job, or his approval is withdrawn.
3. When other conditions under which the licence was granted are not observed, or when the production is not carried out according to the regulations in force and according to proper professional standards.

Approval granted under § 4, paragraph three, may be revoked by the Ministry if, in spite of prior warning, the licensee infringes or neglects his obligations or is regarded as permanently unsuited or unable to be in charge of such manufacture.

PART III

Sale, import and export of medicines.

§ 6
Medicines, with the exemptions provided by law, may only be sold through pharmacies and Norwegian Medical Depot (Norsk Medisinaldepot).

Items deemed to be medicines according to the definitions in this Act but intended for technical, scientific and other non-medical use may be sold by the manufacturers and retailers in accordance with regulations laid down by the Ministry.
The Crown may decide that certain non-prescription, commonly used medicines may be sold by retailers without special licence, but in accordance with regulations laid down by the Ministry.

§ 7
Norwegian Medical depot has the sole right to:

1. The sale to pharmacies of medicines and other substances, drugs and preparations which are intended for use in the preparation of medicines.
2. The import and export of medicines.

The Ministry may, by general regulations or in individual cases, make exemption from the sole rights of the Norwegian Medical Depot.

Norwegian Medical Depot also has the right to sell other items which are used in health care and nursing or which are normally sold by the pharmacies.

§ 8
The sale of medicines from Norwegian Medical Depot is restricted to:

1. Pharmacies.
3. Retailers licensed to sell the same items according to § 9, paragraph two.
4. Public and officially approved laboratories, scientific institutions and other similar institutions or companies as specified by the Ministry.

Subject to rules issued by the Ministry, Norwegian Medical Depot may sell items defined as medicines according to this Act, to purchasers other than those listed above, where it is established that the items will be used for technical, scientific or other non-medical purposes.

The Ministry may also permit Norwegian Medical Depot to sell certain medicines directly to hospitals or other medical institutions.

§ 9
Manufacturers licensed under § 4 may sell the medicines they have manufactured to Norwegian Medical Depot.

When deemed expedient, the Ministry may permit manufacturers and retailers to sell certain medicines to pharmacies and other purchasers as listed under § 8. The Ministry may specify further conditions for such sales.
§ 10
The Crown issues general regulations governing the import and sale of medicines, including those relating to the declaration, statements or certificates required to accompany, or be furnished upon, the purchase or import of medicines and also any precautionary measures which shall be observed upon dispensing.

The Crown issues regulations governing the clinical trial of medicines. These regulations stipulate i.a. what is considered to constitute a clinical trial of a medicine, that such trials shall be approved by the Authority duly appointed by the Crown and the detailed conditions for obtaining approval.

§ 11
The Crown is empowered to forbid the sale of any medicine which is regarded as ineffective, evidently useless or harmful. Prior to such a decision the matter shall be submitted for the Specialities Board (Spesialitetsnemnda) defined under § 19, for its recommendation.

PART IV
The Pharmacopoeia

§ 12
Regulations governing the purity, production, handling and storage, etc, of medicines shall be stated in a Pharmacopoeia which shall be approved by the Crown. The Pharmacopoeia shall also include the instructions relating to the name and description of medicines and dosage forms (nomenclature).

The Pharmacopoeia, including amendments, shall be prepared by the Pharmacopoeia Commission (Farmakopekommissjonen) appointed by the Crown. The Crown issues detailed rules governing the functions of the Commission and the contents of the Pharmacopoeia.

With the exception of those traders selling non-prescription medicines as provided for under § 6, paragraph three, the directions given in the Pharmacopoeia shall apply to all persons permitted to manufacture or sell medicines. The Ministry is empowered to make exemption from these directions in individual cases.

PART V
Pharmaceutical Specialities

§ 13
Within the meaning of this Act, a pharmaceutical speciality is defined as being a medicine not prepared in a pharmacy and which is sold or
marketed in a package intended for the individual consumer (including physician, dentist, veterinarian or hospital).

Where deemed expedient, the Crown may decide that certain medicines produced in a pharmacy and sold to other pharmacies may also be classified as pharmaceutical specialities.

§ 14
Pharmaceutical specialities may not be sold or marketed without prior approval of the Specialities Board, cf. § 19.

Approval is given on the basis of an evaluation of the type of product, its composition, quality and shelf life. Approval shall only be given for products which are medically justified and which are considered to be needed.

§ 15
Approval as a pharmaceutical speciality shall not be given for simple preparations which may be prepared without difficulty in a pharmacy, nor for products which consist of unmixed drugs or chemicals.

Approval shall also be refused for products for which detailed production instructions are given in the current pharmacopoeia, or other approved formulae-compendium.

Exemption from paragraphs one and two of this section may be made where it is considered to be obviously advantageous that a product be produced and sold as a speciality, where the preparation represents a new medical principle, or where other exceptional reasons make an exemption reasonable.

§ 16
Prior to a pharmaceutical speciality being marketed or sold, the name, price, package size and wrapping shall be approved by the authority duly empowered by the Crown.

When approving the price of a pharmaceutical speciality, the price should not be disproportional to its value. In establishing the price, consideration shall be taken to the price of similar products from other manufacturers and to the information available concerning production costs.

Changes in the approved price may be required before the expiration of the registration period if altered circumstances or new information justify such action.

Information relevant to the establishing of the price may be demanded in conjunction with the submission of an application for approval and whenever a revision of the price is under consideration.
§ 17

The approval given for a pharmaceutical speciality is valid for five years. Renewal may not be refused on the grounds given in § 15, paragraphs one and two. A provisional approval may be granted for a shorter period.

When deemed expedient, the approval may be made conditional upon the use of the product being restricted to certain hospitals or doctors.

The approval may be withdrawn before five years have elapsed if:

1. The speciality is no longer regarded as being medically justified.
2. The speciality is not marketed.
3. The composition of the marketed product varies from that for which approval was obtained.
4. A demand for a reduction in price is not complied with within a given time limit.
5. The regulations concerning pharmaceutical specialities are not complied with.

§ 18

The Crown issues detailed regulations concerning the approval, marketing and control of pharmaceutical specialities.

The Crown may grant exemption from the requirements for approval according to § 14 and § 16.

The regulations may stipulate fees to cover the expenses incurred in approving, controlling and evaluating pharmaceutical specialities.

§ 19

The Ministry appoints a Specialities Board which will decide all cases relating to approval of pharmaceutical specialities and the withdrawal of approvals previously granted, according to § 14 and § 17. The Board shall consist of five members including the Director-General of Health as Chairman, one physician, and one person whose qualifications comply with the criteria required for obtaining a pharmacist’s licence. The Ministry issues detailed rules governing the Board.

Decisions of the Board may be appealed to the Ministry, but such appeals are restricted to questions regarding the application of the law.
PART VI

Narcotics, etc.

§ 20
The Crown shall determine which substances, drugs or preparations (narcotics, etc) that shall be subject to the provisions of this Part and shall issue regulations governing the manufacture, marketing (sale, purchase, other transfers and brokerage), import, export, transit, dispensing, distribution and storage of such, together with the cultivation of plants used in the production of such items.

The regulations may provide for the prohibition of the production, acquisition, sale, import, export and transit of certain narcotics, etc. The regulations shall also apply in free-ports and bonded and transit warehouses.

§ 21
Narcotics, etc, may be produced only to the extent expressly provided for under the terms of the licence granted according to §§ 4 or 33.

Unless otherwise provided for in the regulations, each import, export and transit of narcotics, etc, may only take place under permit, or as otherwise provided for in the regulations. Such permit is issued by the authority duly appointed by the Crown.

The marketing, dispensing and distribution of narcotics, etc, for medical and scientific purposes must be in accordance with the regulations in force.

Manufacturers and suppliers are required to furnish the reports and information demanded by the Ministry.

§ 22
In the absence of legal right, it is forbidden to be in possession of, or to use, narcotics, etc, and to obtain or purchase such under false pretences e.g. by giving false information about name, address, illness or symptoms of illness.

Such preparations may not be used for purposes other than those for which they are supplied and, without legal authority, they may not be transferred to, or acquired by, others than the person to whom the prescription or requisition is issued. The prescription or requisition is non-transferable and may not be utilized by anyone other than the person to whom it is issued.
Statutory (professional) secrecy shall not preclude the forwarding to the Director-General of Health of information regarding the possible abuse of narcotics, etc.

Physicians, dentists, veterinarians, pharmacy owners and managers, psychologists, temperance boards and police are required to supply information upon demand to the Director-General of Health concerning specified persons possible abuse of narcotics, etc, or concerning other specified instances of abuse or infringement of the regulations and laws governing these substances. In legal actions involving sentence or seizure consequent to infringement of such regulations, the Courts may hear evidence notwithstanding the provisions of § 119 of the Criminal Procedure Act.

Information concerning abuse given to the Director-General of Health in accordance with the provisions of this section, or which may have some to his attention by other means, may be communicated by him without hindrance of professional secrecy to physicians, pharmacies, psychologists, temperance boards and also to the police if there is reason to suspect any infringement of the law.

With the exception of the right to pass confidential information to the police, the Director-General of Health may delegate the powers invested in him by the terms of this section.

PART VII

Sera, vaccines and other bacteriological and serological preparations.

§ 24
Sera, vaccines and other bacteriological and serological preparations may be manufactured, sold, imported and exported by officially approved laboratories or institutes in accordance with directions issued by the Ministry.

The Ministry decides what shall be deemed to be sera, vaccines, bacteriological or serological preparations, and may also permit the sale of certain other articles for medical or veterinary purposes by the mentioned laboratories or institutions.

PART VIII

Spirits, liquor and wines intended for medicinal purposes.

§ 25
The Crown issues regulations defining the terms spirits, liquor and wines for medicinal purposes and governing the sale and dispensing of such items.
General restrictions upon the rights of physicians, dentists and veterinarians to prescribe or require spirits, liquor and wines for medicinal purposes may be incorporated into these regulations.

§ 26
The Ministry is empowered to withdraw for a stipulated period the right to prescribe or require spirits, liquor or wines for medicinal purposes from any physician, dentist or veterinarian who infringes the regulations according to § 25, or who otherwise abuses these rights, or who is convicted for an infringement of the general laws governing alcoholic beverages.

The Ministry is empowered to curtail the rights of a pharmacy to purchase spirits, liquor or wines for medicinal purposes where there is just cause to suspect irregularities surrounding the dispensing or use of such items.

§ 27
It is prohibited to obtain access to purchase spirits, liquor or wines for medicinal purposes by false pretences, e.g. false name, address, illness or symptoms of illness.

Spirits, liquor or wines dispensed for medicinal purposes shall not be used for any other purpose, nor, in absence of legal authority, shall they be handed over to any person other than the one to whom the prescription or requisition is issued.

PART IX

Certain items which are not medicines.

§ 28
The Crown may decide that certain items which are not classified as medicines within the meaning of this Act, but which are sold for specific medical use, or for other particular uses in health care or nursing, shall nevertheless be subject to special control to ensure compliance with safeguards for life and health.

Regulations regarding such control are issued by the Crown. The regulations may stipulate rules for standards to be met for approval of the item itself, for the manufacturers and retailers and for the supervision of the manufacturing and marketing. Fees to cover the expenses for evaluation, control and approval may be stipulated in the regulations.
PART X
Advertising of medicines, etc.

§ 29
Advertising of medicines shall be moderate and true and shall be subject to prior approval by the authority duly appointed by the Crown.

The Crown issues regulations governing advertising for medicines, including the distribution of samples for advertising purposes. The regulations may prohibit certain forms of advertising.

§ 30
For any product sold by means other than those approved for the sale of medicines, it is prohibited by way of advertisement or similar device, by text or illustration, directly or indirectly, to promote the said product for the purposes of prevention, healing or alleviation of human and animal illness or pain. When deemed expedient, the Ministry may make exemptions from this provision.

In the event of violation of this provision the Ministry may direct the manufacturer or advertiser to issue or publish an approved correction in the same manner in which the illegal advertisement has been issued or published.

If, in spite of warning, the product continues to be advertised in contravention to the provisions contained in the first paragraph, the court may prohibit the sale of the said product under the name used in the offending advertisement.

§ 31
Advertisements shall not, by text, illustration or any other means, directly or indirectly, give false, misleading or deceptive information regarding any medical effects or qualities of the product. The penultimate and ultimate paragraphs in § 30 also applies.

When deemed expedient, the Crown is entitled to issue regulations, or in specific instances, to prohibit all medical advertising to the general public for specified products or groups of products.

PART XI
Poisons and substances injurious to health.

§§ 32–38
PART XII

Miscellaneous provisions.

§ 39
If there is any doubt as to whether a product intended for import or marketing contains substances regulated by this Act, the Ministry may require from the manufacturer or importer sufficient information as to the composition of the said product to resolve the question.

The Ministry may prohibit the import or sale of the said product until such information is provided.

§ 40
Any person having medicines in his possession is responsible for keeping them with care and attention.

§ 41
Any person who, by virtue of his position or duties in administering the law, obtains knowledge of any industrial or commercial secret, shall not, subject to the limitations imposed by the prosecution of his duties in accordance with the law, disclose the said information. Such information so obtained may not be used for professional gain. The Ministry may make exemptions from the professional secrecy in this section, when deemed expedient for strong public reasons. The Public Administration Act of 10 February 1967, (forvaltningsloven), § 13–13 e shall not apply.

§ 42
Any persons obtaining a licence under the terms of this Act for the purpose of manufacture, sale, import or export of medicines, does so in the knowledge that the rights or obligations so acquired in accordance with the law, may at any time, be amended by subsequent legislation or by new general regulations issued in accordance with the law.

Licences may also be issued for limited periods only.

PART XIII

Penalties. Seizure.

§ 43
Any person who, whether by intention or negligence, violates this Act or the provisions or directions of this Act, is punishable by fines or by imprisonment of up to 3 months, or both.

Possession and use of narcotics etc, cf. § 22, paragraph one, is punishable by fines or by imprisonment of up to 6 months, or both.

If the punishable offence relates to any form of transfer of medi-
cines not classified as narcotics and the circumstances are especially aggravating, the penalty shall be fines or imprisonment of up to 2 years, or both.

Complicity is similarly punishable. Attempted infringement is regarded as an accomplished offence and is punishable thereafter.

§ 44

(Repealed by Act of 26 January, 1973, No 2.)

§ 45

The Ministry rules upon the fate of any medicines seized. The Ministry also rules upon the fate of narcotics, etc where ownership is not established.

PART XIV

Implementation, Transitional provisions.

§ 46

This Act comes into force at the time duly appointed by the Crown.* Concomitant with this Act coming into force, the following legislation is repealed:

§ 47

The following amendments in the Act of 8 March, 1935, relating to trade and commerce, will come into force from the same date as this Act:

§ 48

Regulations issued in accordance with the Acts mentioned in §§ 46 and 47 remain in force provided they are not incompatible with this Act until such time as their being rescinded or replaced by regulations issued in accordance with this Act.

Permits and approvals granted in accordance with the Acts mentioned in §§ 46 and 47 remain valid until further notice, provided they are not incompatible with this Act or provisions to this Act. The Ministry is empowered to require that such permits and approvals be renewed under the terms of this Act and that all applications for permits or approvals shall be submitted by a final date that the Ministry shall determine and publish.

* From 1 April, 1965, by Royal decree of 20 November, 1964.