

# Norwegian Act No. 17 of 21. June 1963 concerning The Operation of Pharmacies, etc.

(Norsk Lovtidend, 1963, Part 1, 26. July 1963, No. 23, pp. 665—679)

## PART I

### *Establishment and closing of pharmacies*

§ 1. The Crown\*) shall determine whether pharmacies shall be established or closed. Before the decision is taken, the local authorities (kommunestyre), board of health, public health officer, and the county chief administrative officer (fylkesmann) concerned shall be given an opportunity to express their opinions.

A pharmacy shall be established when this is desirable or necessary from the point of view of the public. The board of health or the local authorities concerned shall be responsible for raising the question of the establishment of a new pharmacy when there is a need for it.

Pharmacies may be established as independent pharmacies, branch pharmacies, in conformity with the provisions of Part XI, or as hospital pharmacies, in accordance with the provisions of § 45.

§ 2. The Ministry shall determine, after the local authorities concerned has given his opinion, where the pharmacy shall be located within the area in which it has been laid down that it shall be established. The pharmacy may not be moved without the approval of the Ministry.

The pharmacy shall have a name approved by the Ministry. The Ministry shall be empowered to order that the name of the pharmacy shall be changed. In the case of a branch pharmacy, it shall be indicated, in an addendum to the name, of which pharmacy it is a branch.

## PART II

### *Trade and manufacture in pharmacies*

§ 3. A pharmacy shall have the right to trade in pharmaceutical products and poisons, dressings, medical equipment and other articles which are used in medical treatment.

Other articles may also be sold in a pharmacy, when their sale can be naturally and appropriately combined with the normal trade in pharmaceutical products, etc.

The Ministry, by making general rules or specifically for an individual pharmacy, may limit the right to trade in articles which are not pharmaceutical products.

§ 4. Pharmacies shall be obliged, provided that no other provisions are laid down, to trade in all pharmaceutical products which

\*) By virtue of the provisions of the Crown Decision of 4. October 1963, the duties of the Crown provided for by this Act devolve upon the Minister of Social Affairs.

are permitted to be sold in Norway, together with the usual dressings and medical equipment.

The Crown, by making general rules or specifically for an individual pharmacy, may order that the trade shall be carried on in other articles which are used in medical treatment.

When special reasons for so doing exist, the Ministry can grant exemptions from the said obligation.

§ 5. Provided that no other provisions are laid down, a pharmacy shall have the right to manufacture or prepare those pharmaceutical products and other articles which it is entitled to sell. The Ministry, by making general rules or specifically for an individual pharmacy, shall be empowered to restrict the manufacture of certain types of article.

Manufacture for sale to other pharmacies shall be subject to a special licence from the Ministry, which shall lay down the conditions and rules for such manufacture and for its control.

§ 6. When a pharmacy is established or changes ownership, the Ministry shall have the power to order:

- a) that the right of the pharmacy to manufacture or prepare pharmaceutical products or other articles shall include only simple preparations according to a prescription, or the like, or that this right shall cease completely. A similar decision can also be taken in other cases, if the owner of the pharmacy agrees to this;
- b) that the pharmacy shall carry on the manufacture of certain pharmaceutical products for sale to other pharmacies. When special reasons for so doing exist, such an order may also be given in other cases.

### PART III

#### *Licenses for pharmacies. Pharmacists*

§ 7. The operation of a pharmacy shall be subject to a licence granted by the Crown. When special reasons for so doing exist, the Crown shall be empowered to order that a pharmacy shall be operated by the State.

Licences may be granted to persons who satisfy the conditions laid down in § 8, or when special reasons for so doing exist, to the Norwegian Medical Depot (Norsk Medisinaldepot) or to urban or district municipalities, or provinces, under the conditions laid down in Part XII.

Within the meaning of this Act, persons who possess a licence to operate a pharmacy, or who have been appointed to be in charge of a pharmacy operated by the State, the Norwegian Medical Depot or by the local authorities, shall be called pharmacists (apoteker).

§ 8. To become a pharmacist, an applicant must prove that:

- I he has passed the examination for pharmacists;
- II after qualification, he has completed at least five years' service in a Norwegian pharmacy. In special cases, this period can be reduced when the applicant has had long and varied experience in some other pharmaceutical activity;
- III he has passed examinations which satisfy the requirements for obtaining the permit to engage in commercial activities (handelsbrev);
- IV he is solvent;
- V he is of good moral character.

§ 9. The licence to operate a pharmacy shall involve the right and duty to operate it in conformity with the provisions of this Act and the instructions and regulations which are made for its enforcement.

The licence may lay down special conditions or duties, when the applicant has been made acquainted with these beforehand.

The holder of a licence to operate a pharmacy may, without compensation, be called upon to accept changes in his rights and duties, as the result of the introduction of a new law.

§ 10. The licence to operate a pharmacy shall cease to be valid when:

- I the holder receives a licence to operate another independent pharmacy. This provision shall not apply, however, to pharmacies operated by the State, by local authorities or by the Norwegian Medical Depot;
- II the holder is released from his obligations in conformity with the provisions in force with regard to pensions and age limits;
- III the holder, at his request, is released from his obligations;
- IV the holder has died and the right of the spouse or the heir to operate the pharmacy, in conformity with the provisions of § 11 has expired;
- V the holder has been declared bankrupt, and has not, within a period of one year of this declaration, been discharged from bankruptcy;
- VI the licence has been withdrawn by the Crown, in conformity with the provisions of § 12, or ceases to be valid, in conformity with the provisions of § 13;
- VII the holder, on the basis of a final decision of a court of law, has been deprived of the right to operate a pharmacy.

The licence shall cease to be valid from the day on which the pharmacy is taken over by a new owner. The owner shall be responsible for the operation of the pharmacy until the licence ceases to be valid, but not, however, for longer than one year from the day on which the request to be released has been submitted.

§ 11. If the holder of a licence to a operate a pharmacy dies, his spouse or heir shall have the right to continue the operation of the pharmacy with an approved manager for a period of six months from the date of the death.

If the death occurs less than five years after the deceased took over or opened the pharmacy, the Ministry, when special reasons for so doing exist, may permit the spouse or heir to continue the operation of the pharmacy until the period of five years from the taking over or opening has been completed.

The provisions of the preceding paragraph shall apply correspondingly when the pharmacy has been moved or completely rebuilt within the five years before the death occurred or if the holder of the licence dies before the taking over or opening has taken place.

§ 12. The Crown shall have the power to withdraw a licence to operate a pharmacy:

- I when the pharmacy has not been taken over or established within the period laid down by the Ministry;
- II when the premises, installations and equipment or stores are kept in such a bad state that the situation must be considered as intolerable, and are not improved, in spite of a warning having been given, within the period fixed by the Ministry;
- III when the holder, in spite of a warning having been given, commits a serious infraction or neglects his duties, or by his behaviour fails to inspire the respect and confidence required for a person to be entitled to hold the permit to operate a pharmacy;
- IV when the holder may be considered as unsuitable to operate a pharmacy in a reasonable manner.

Before the decision is taken, the holder shall be acquainted with the grounds for the proposed withdrawal of the licence together with the information on which it is based, and given an opportunity to state his case.

A lawsuit to determine the legality of the withdrawal of a licence shall suspend such withdrawal.

§ 13. A licence to operate a pharmacy shall cease to be valid if it is determined, as the result of a reorganization of the pharmaceutical trade, that the pharmacy shall be operated by the State. In such a case, the pharmacist shall receive a compensation for the fittings, equipment and stocks of the pharmacy, and shall be given preference in the appointment of a manager for it.

#### PART IV

##### *Taking over of pharmacies*

§ 14. A person who takes over a pharmacy, when the previous owner, his spouse or his heir so request, shall be obliged to take over the fittings, equipment and stocks of this pharmacy, to the

extent that they are in a condition suitable for use and do not exceed the normal requirements of the pharmacy.

The new owner can demand that the fittings and equipment, acquired by the pharmacy, and which are considered necessary for the operation of the pharmacy, shall be taken over by him.

In the event of any dispute as to whether a take-over shall be effected pursuant to this paragraph, or as to the price or take-over terms, such dispute shall be settled by valuation, unless the parties agree to let it be settled by arbitration undertaken by a committee of three members appointed by the Ministry.

§ 15. Any take-over agreement pursuant to § 14 requires the approval of the Ministry. If approval is refused, the parties may choose whether to let the dispute be settled by arbitration according to § 14 last item, or by valuation.

#### *PART V*

##### *Operation of pharmacies*

§ 16. Pharmacies shall be under the direction of the pharmacist himself or of a manager approved by the Ministry.

The pharmacist or the approved manager shall be personally responsible for the day-to-day management of the pharmacy and must ensure that the activities are carried out in conformity with the legal provisions in force. He shall ensure that the pharmacy is managed by a responsible person when he himself is not present.

The Ministry shall make regulations as to the management of pharmacies in the absence of the pharmacist or of the approved manager.

§ 17. An approved manager of a pharmacy must satisfy the conditions for the granting of the licence to operate a pharmacy. The Ministry shall have the power to grant exemptions from the requirements laid down in items 2 and 3 of § 8 when the manager is appointed for a period of less than six months, or when special reasons for so doing exist.

§ 18. A manager shall be appointed when a pharmacist has been, or will be, absent from the pharmacy for more than three months. Apart from the cases mentioned in § 11, permission to appoint a manager shall be given only for one year at a time.

The Ministry shall have the power to order the holder of a licence to operate a pharmacy to appoint an approved manager:

I when it is assumed that there are grounds for the withdrawal of the licence, in conformity with the provisions of § 12, or when the pharmacist has been accused of criminal conduct which may entail the withdrawal of the licence. The decision as to the withdrawal shall, in such a case, be taken as soon as possible;

- II when the pharmacist, by reason of illness or infirmity or for other causes, is not capable of managing the pharmacy, or when he has shown, by his negligence, that he cannot manage it in a satisfactory manner;
- III when the owner, by the irresponsible management of his affairs, harms his economic position to such an extent that there is a serious danger that he will be unable to perform his duties.

The Ministry shall be empowered to appoint a manager on behalf of the owner, if he does not obey the requirements of the order within a period which it shall lay down.

#### PART IV

##### *Staff*

§ 19. A pharmacy shall be adequately staffed in relation to the type and scope of the manufacture and trade carried out.

The Ministry shall have the power to determine how large the staff of a pharmacy shall be, and in this connexion, how many of the staff shall be qualified pharmacists, how many shall have received training as assistant pharmacists (reseptarutdanning) or other approved training in pharmacy, or any other form of training as may be indicated.

The Ministry shall determine what shall be considered as an approved training in pharmacy.

§ 20. By the right to supply pharmaceutical products and poisons shall be understood the right independently to supply goods which, in conformity with the regulations in force with regard to such supply, must bear a label with the name of the supplier. This right shall be possessed only by qualified pharmacists, or by persons who have received training as assistant pharmacists or other approved training in pharmacy.

The manufacture, preparation and bottling, together with the labelling, delivery and other handling of pharmaceutical products and poisons, shall take place under the responsible technical control of a person who possesses the right to supply such products, and who shall be responsible for ensuring that the legal provisions in force are obeyed.

§ 21. Pharmacies shall be obliged, as determined by the Ministry, to establish the conditions under which students of pharmacy and pupil assistant pharmacists may receive practical training.

The Ministry may determine which pharmacies shall be permitted to take such persons for training.

§ 22. Persons employed in pharmacies who wish to undergo further professional training for their work, shall, in general, be given permission to undergo such practical training as may be required, provided that they:

- I are less than 25 years of age;
- II have worked for at least one year in a pharmacy, and have undertaken the normal work of an assistant;
- III satisfy the other requirements laid down for acceptance as a pupil or take the necessary examination.

Such a person must inform the pharmacist or manager of a pharmacy that he wishes to undergo such training, and can require, within a period of one month, an answer containing plans and conditions for further training, or to the effect that the training in question cannot be carried out in the pharmacy.

§ 23. Pharmacists and all pharmacy staff shall be obliged, with the exceptions laid down in this Act or pursuant to it, to observe secrecy in respect of all information entrusted to them in the practice of their profession, or of which they thereby become aware, in respect of the physical condition or illness of a person.

This obligation to observe secrecy shall not prevent pharmacists or managers of pharmacies from making reports or giving information to the Director-General of Health as to the misuse of narcotics.

The pharmacists must ensure that all staff employed in the pharmacy are made aware of their obligation to observe secrecy.

§ 24. Pharmacists and pharmacy staff must not, except where urgent assistance is required, treat patients or give medical advice.

Staff who have the right to supply pharmaceutical products may, on request, give reasonable advice on pharmaceutical products and their use.

## PART VII

### *Premises, fittings and equipment*

§ 25. The holder of a licence to operate a pharmacy shall be obliged to provide for the pharmacy such premises, fittings and equipment as shall be approved by the Ministry.

On the taking over or establishment of a pharmacy, the owner shall be obliged, if so required by the Ministry, to rent such premises as shall be indicated by the Ministry, provided that the rent and other conditions are not unreasonable in relation to the usual conditions for the renting of business premises in the place concerned.

The Ministry shall be empowered to make regulations as to the premises, fittings and equipment for pharmacies. It shall have the power to require that agreements for the renting of premises for pharmacies shall be submitted to the Ministry for approval.

§ 26. On the occasion of the establishment, re-equipping, enlargement or change of premises of a pharmacy, plans must be submitted beforehand to the Ministry.

The Ministry shall be empowered to order that a pharmacy shall be re-equipped, enlarged or moved to new premises, if its existing

premises are too small or unsuitable, and to order the owner, within a given period of time, to submit the necessary plans for approval. If such an order is not obeyed, the Ministry shall be empowered to require that the re-equipping, enlargement or movement to new premises shall be carried out in accordance with plans that it shall draw up.

#### PART VIII

##### *Supply, inspection, responsibility, etc.*

§ 27. During such hours of opening or duty periods as shall be determined by the Ministry, the pharmacy shall supply, as quickly as possible, the pharmaceutical products, dressings and medical equipment required.

The Ministry shall be empowered to make regulations in this connexion, and also to determine that the supply of certain articles may not be required outside the normal hours of opening.

§ 28. When physicians, dentists or veterinarians prescribe, for medical purposes, pharmaceutical products or other articles which are not available in the pharmacy, steps must be taken immediately to obtain them as quickly as possible.

If it is stated on a prescription from a physician, dentist or veterinarian that a pharmaceutical product is urgently required, or if the pharmacy is otherwise informed of this, the product shall be supplied even if payment is not forthcoming or not guaranteed.

§ 29. The obligation of a pharmacy to supply pharmaceutical products, etc., shall not apply to articles subject to the regulations on narcotics, or other products which may be misused, when the pharmacy has received notification from the Director-General of Health that such an article may not be supplied to a certain person.

§ 30. The pharmacists or the manager of the pharmacy shall ensure that pharmaceutical products which are bought for the pharmacy, or manufactured or prepared there, are tested in the technically appropriate manner and in conformity with the legal provisions in force.

In the case of pharmaceutical specialities and other products which are bought in the original packages and which are supplied to the user in these packages, the tests can be restricted to making sure that there are no external signs of any fault or defect.

§ 31. The manufacture, preparation, storage and handling of pharmaceutical preparations in a pharmacy shall be carried out in the manner prescribed in the pharmacopoeia, or in conformity with other instructions issued by the Ministry.

Pharmaceutical products included in the pharmacopoeia shall satisfy the tests laid down in it.



§ 32. Pharmaceutical products must always be supplied precisely in accordance with the prescription or request.

The provisions of § 30 shall apply correspondingly to the supply of such products.

The Ministry shall be empowered to make regulations as to the supply of pharmaceutical preparations, poisons and other articles by pharmacies.

Price regulations for the sale of pharmaceutical preparations etc., from pharmacies shall be issued by the Crown.

§ 33. In the event of any personal injury or material damage resulting from faulty or deficient pharmaceutical products or poisons supplied by a pharmacy, the owner of the pharmacy will be liable for compensation, even if neither he nor any member of the pharmacy staff has been negligent. The same rule applies in the event of incorrect signing or delivering of the product. Such unconditional liability will however not arise if the pharmaceutical product or poison has been supplied in exact accordance with a prescription or order and has been signed and delivered in accordance with the regulations in force.

The provisions of the first paragraph entail no restriction of any right to claim compensation pursuant to the general rules of law.

For the purpose of securing performance of any liability payment under this section, all pharmacies shall take out liability insurance in accordance with rules issued by the Ministry, or place other security acceptable to the Ministry.

§ 34. Pharmacies shall keep adequate stocks, in relation to the type and extent of the trade which they carry on, and shall always keep stocks of such pharmaceutical products as are commonly prescribed by physicians, dentist or veterinarians in the locality concerned, and of the usual dressings and medical equipment.

The Ministry shall be empowered to make rules as to the articles which must always be kept in stock by a pharmacy.

§ 35. All pharmaceutical products and substances which are to be used for the preparation of such products, shall be bought by pharmacies, unless the Ministry determines otherwise, from the Norwegian Medical Depot or from pharmacies which have been given permission to sell to other pharmacies.

#### PART IX *Accounts, etc.*

§ 36. Pharmacies shall keep proper and complete accounts in accordance with rules issued by the Ministry, which may also issue rules concerning the auditing of said accounts.

The Ministry may order the pharmacies to keep other books concerning their operation.

Accounts and other books shall be sent to the Ministry for inspection and auditing whenever required, and shall upon demand be produced for inspection by a pharmacy inspector or other duly empowered persons.

§ 37. Before such dates as will be stipulated, the pharmacies shall submit extracts of the accounts and other books, and such statements, reports and information as are required by the Ministry.

## PART X

### *Taxes*

§ 38. All persons licenced to operate a pharmacy shall pay to the Treasury a tax which will be stipulated by the Storting (Parliament) each year.

Further rules for calculating and collecting the pharmacy tax and for the control thereof, will be issued by the Crown.

As regards collection of the pharmacy tax, the rules applying to capital and income tax to the State will similarly apply.

The Ministry may upon application waive all or part of the claim for pharmacy tax, if the accounts for a pharmacy show that its operation has failed to provide its owner with reasonable earnings.

§ 39. The pharmacy tax revenues each year shall be employed as decided by the Storting. Any surplus will be transferred to the Pharmacy Tax Fund.

The Storting will determine the purpose for which the assets of the Pharmacy Tax Fund shall be employed.

## PART XI

### *Branch pharmacies. Shops for the sale of medicines*

§ 40. A branch pharmacy shall be established when this is considered desirable to facilitate the provision of pharmaceutical products to the population, and when there are no grounds for the establishment of an independent pharmacy. On the establishment of such a branch pharmacy, it shall be determined to which independent pharmacy (main pharmacy) it shall belong.

The Crown shall be empowered to order:

- I that an independent pharmacy, when it becomes vacant, shall be converted into a branch pharmacy;
- II that a branch pharmacy, when this is required for the benefit of the public, shall be converted into an independent pharmacy. The owner of the main pharmacy, in such a case, shall be given reasonable notice, and shall be given preference in the granting of the permit to operate the new independent pharmacy;

III that a branch pharmacy, when it becomes vacant, or with the agreement of the owner, shall be transferred to another pharmacy;

IV that the owner of an independent pharmacy shall be obliged to establish and operate a branch pharmacy.

§ 41. Branch pharmacies, in general, shall not manufacture pharmaceutical products or other articles, but may undertake simple preparations from prescription, and the like. The Ministry shall be empowered to limit the right of a branch pharmacy to undertake such preparation, and may, in special cases, give permission for manufacture and preparation on a wider basis than that indicated in the preceding sentence.

The Ministry shall be empowered to make rules as to the operation of branch pharmacies.

§ 42. A branch pharmacy shall be under the control of a manager approved by the Ministry. Vacancies shall, in general, be advertised to the public.

A manager must be a qualified pharmacist, have undergone training as an assistant pharmacist or other approved training in pharmacy, have completed at least two years' service in a Norwegian pharmacy after having passed the examination, have an adequate knowledge of book-keeping and be of good moral character.

§ 43. The Ministry shall be empowered to permit a pharmacy to operate a shop for the sale of medicines (*medisinutsalg*) in places other than that in which the pharmacy is situated, and if necessary, order that a pharmacy shall operate such a shop.

The Ministry shall have the power to make rules as to the establishment and operation of shops for the sale of medicines.

## PART XII

### *Pharmacies operated by public authorities. Hospital pharmacies*

§ 44. Pharmacies which are operated by communes shall have their own management and budget, to the extent to which this is permissible under the legislation on communal administration.

The Crown shall appoint pharmacists to pharmacies operated by the State, the Norwegian Medical Depot or by municipalities, but in the last two cases, after the holder of the licence has given his opinion. The instructions for the pharmacist shall be laid down or approved by the Ministry.

§ 45. Hospital pharmacies may be established in order to supply pharmaceutical products, etc., to hospitals or other medical establishments or public institutions.

Hospital pharmacies may be independent or branch pharmacies. Independent hospital pharmacies shall be operated by the State, the Norwegian Medical Depot or a municipality.

The Ministry shall determine to which hospitals, etc., the hospital pharmacy shall supply goods, and may agree that the staff of the institute in question and the patients undergoing treatment there shall also be supplied.

When special reasons for so doing exist, the Crown may permit a hospital pharmacy also to sell goods to the public.

§ 46. Pharmacies belonging to the armed forces (field pharmacies) shall not be subject to the provisions of this Act, unless the Crown shall determine otherwise. The Crown shall be empowered to make rules as to their activities. They shall not be permitted to sell pharmaceutical products.

### PART XIII

#### *Inspections of pharmacies*

#### *Control of pharmaceutical products*

§ 47. The inspection of pharmacies shall be carried out by the public pharmacy inspectors, the competent public health officers or by other persons appointed for this purpose by the Ministry. The Ministry shall be empowered to make rules as to the inspection of pharmacies.

In the course of an inspection, or at other times, when this appears desirable, samples of pharmaceutical products and of other articles may be removed free of charge for further investigation and testing.

Faults which are found on inspection or on the examination of goods, shall be corrected as soon as possible.

### PART XIV

#### *Miscellaneous provisions*

§ 48. The word «pharmacy» and compound words which contain this word, may not be used as the designation for any business or activity which is not a pharmacy in conformity with the provisions of this Act, nor for articles which are not articles supplied by pharmacies. Neither shall such designations be used in connexion with advertisements for articles which are not articles supplied by pharmacies.

The Ministry shall be empowered to grant exemptions from these provisions for firms and trademarks which were registered or were in use before 1. January 1962.

§ 49. Physicians and veterinarians may be given permission by the Ministry to supply pharmaceutical products, dressings and other medical equipment in return for payment when access to a pharmacy is difficult. Pharmaceutical products shall be obtained ready prepared from a pharmacy.

The Ministry shall be empowered to make rules as to the supply of pharmaceutical products, etc., as provided for in the preceding paragraph, and in particular as to the prices or profit permitted.

§ 50. Even if permission as mentioned in § 49 has not been granted, a physician, dentist or veterinarian may claim repayment of his costs for pharmaceutical products which he has used during the treatment of a patient or an animal, or which he has supplied for use until such products can be procured from a pharmacy. The kind, quantity and price of such products shall be specified in the bill.

§ 51. In areas where access to a pharmacy or a physician is difficult, the provincial medical officer of health may permit an officially recognized nurse to keep a small store of pharmaceutical products, etc., for use in appropriate cases. No profit shall be made on supplies from such a store. The goods shall be supplied by a given pharmacy which shall be responsible for the necessary control.

§ 52. The Crown shall be empowered to make regulations for the completion and enforcement of this Act.

#### PART XV

##### *Penal provisions, etc.*

§ 53. Pharmacists and pharmacy managers, including managers of branch pharmacies, shall have the same penal liability as civil servants.

§ 54 Any intentional or negligent violation of the provisions contained in the present Act or issued pursuant thereto, is punishable with fines or imprisonment for up to three months, unless more severe punishment may be imposed pursuant to other provisions.

§ 55. Pharmacists who fail to submit required statements or reports by the stipulated date, may be ordered by the Ministry to pay a current fine of up to Kr. 10.— for each day from the date on which they receive such order until the date on which said statements reach the Ministry.

The said fines will accrue to the Pharmacy Tax Fund.

#### PART XVI

##### *Entry into force. Temporary provisions*

§ 56. (Entry into force. Repeal of Act of 4 August 1909 on the operation of pharmacies, and of Act of 25 July 1910 on the supply of pharmaceutical products, etc., by physicians and veterinarians).

§ 57. The provisions of item 3 of § 8 to the effect that a person who wishes to become a pharmacist must have passed examinations satisfying the requirements for obtaining the permit to engage in commercial activities shall not apply to applicants who are more than 45 years old on the entry into force of this Act.

§ 58. (Amendments to the Act of 8 March 1935 on trade).