

THE LAW OF PHARMACY

The Parliament of Romania hereby adopts this law.

CHAPTER I General matters

Art. 1. - In accordance with this law, pharmaceutical assistance for the population shall be ensured through community pharmacies and drugstores.

Art. 2. - (1) The community pharmacy provides pharmaceutical care to the population through the following activities:

- a) release for retail price of on-prescription medicinal products;
 - b) release for retail price, under legal provisions, of non-prescription medicinal products;
 - c) preparation of magistral and officinal medicinal products or other healthcare products;
 - d) release of medicinal products for veterinary use;
 - e) sale of cosmetic products, parapharmaceuticals, medical devices and equipment for personal use and supplies thereof, food supplements and foods for special purposes, harmless plants and harmless herbal products, child care products, personal hygiene items, equipment, materials or products for health protection or improvement, products for protection against sexually transmitted diseases or contraception action, homeopathic products, products for aromatherapy and other products for use in certain pathological conditions;
 - f) information and counselling of patients on proper and rational use of medicinal products and maintenance of health;
 - g) testing of certain biological parameters with equipment for individual use by patients as well as administration of vaccines, as provided by order of the minister of public health.
- (2) "Self-service" sale of medicinal products for human or veterinary use is prohibited in community pharmacies.
- (3) Supply of medicinal products is only performed in community pharmacies or drugstores.
- (4) Supply of medicinal products for human use is prohibited in veterinary pharmacies.
- (5) The community pharmacy takes part in programs and campaigns for health promotion and care, according to professional skills of its staff.
- (6) Supply of medicinal products is retail only, except for emergency kits required by law.

Art. 3 - (1) Pharmaceutical activities in hospital settings or other facility requiring a close circuit pharmacy is organised as laid down by order of the minister of public health.

(2) Under the conditions laid down by order of the minister of public health, hospital pharmaceutical care may be outsourced to community pharmacies.

Art. 4. – Drugstores provide pharmaceutical care to the population by means of activities under Art. 2. (1). b), e) and g), except for sales of homeopathic products.

Art. 5. - (1) Activities referred to in Art. 2. (1). a), c), d) and f) are performed by pharmacists only.

(2) Activities referred to in Art. 2. (1). b), e) and g) may also be achieved by pharmacy assistants in the community pharmacy or drugstore, except for sale of homeopathic products, which are available on prescription only.

CHAPTER II

The Community Pharmacy

SECTION 1

Establishment of the community pharmacy

Art. 6 .- (1) The community pharmacy is established and operates within a trading company organised under provisions of Law no. 31/1990 on trading companies, republished as amended.

(2) The object of companies under (1) is retail sale of pharmaceuticals.

Art. 7. - Community pharmacies are headed by a chief pharmacist. The chief pharmacist position may be held by pharmacists entitled to free practice.

Art. 8. - (1) The community pharmacy operates based on the operating authorisation issued by the National Medicines Agency, in accordance with this law.

(2) The activity of community pharmacies is conducted in accordance with Good Pharmaceutical Practice regulations developed by the Ministry of Public Health in consultation with the College of Pharmacists in Romania, and approved by order of the minister of public health.

Art. 9. – The authorisation for operation under Art. 8 (1) grants the following rights:

a) the right to conduct activities under the law;

b) the right to own, prepare and supply, under the law, toxic and psychotropic substances and products or their precursors used for medical purposes;

c) the right to own, to prepare and issue, under the law, substance and drug products or their precursors, used for medical purposes;

d) the right to contract provision of pharmaceutical services with health insurance companies.

Art. 10. - (1) The authorisation for operation under Art. 8 (1) is granted in the name of the legal entity and the chief pharmacist of the pharmacy by the National Medicines Agency.

(2) For grant of the authorisation for operation under Art. 8 (1), the Applicant shall submit the following documents:

a) application form;

b) notice of opportunity on the opening of the unit, issued to bodies under (1) based on the advisory opinion of the College of Pharmacists in Romania, issued by the Ministry of Public Health through public healthcare authorities, and is not transferable;

c) the full time employment contract or proof of liberal exercise of the profession for the chief pharmacist of the unit and the certificate of membership to the College of Pharmacists in Romania, issued under the law, accompanied by the current professional certificate issued by the College of Pharmacists in Romania;

d) pharmacists' job descriptions, approved by the College of Pharmacists in Romania;

e) the set up documents of the trading company referred to in Art. 6. (1);

f) a copy of the Applicant's certificate of registration in the Trade Register Office;

g) the ascertaining certificate issued by the Trade Registry Office, indicating registration as a work area of the space for community pharmacy or, where applicable, of the registered activity office for which authorisation is sought;

h) the blue print and data on unit premises;

i) the list of endowment with furniture, utensils and equipment, analysis table, according to the order of the minister of public health.

(3) The documentation referred to in (2) shall be submitted to the Ministry of Public Health within 45 days as of issuance of the notice of opportunity in Art. 12. For objective reasons, the Ministry of Public Health may extend this period for successive 30-day periods not exceeding 90 days.

(4) The 45-day term referred to in (3) is a period of revocation for the Applicant. If the Applicant does not submit the documentation referred to in

(2) within the said period, a new notice of opportunity has to be acquired for the authorisation for operation.

(5) The authorisation for operation under Art. 8 (1) is granted following a favourable inspection report provided by the Pharmaceutical Department within the Ministry of Public Health, through public health authorities, which have personnel specialised in this regard. The inspection is conducted within 60 days after submission of the documentation specified in (2).

(6) In case of unfavourable inspection reports, a 45-day term is provided for remedy of deficits found.

(7) The authorisation for operation granted under this law includes the health authorisation for operation, the authorisation for possession and handling of toxic substances and products, narcotics, psychotropic substances and precursors used for medical purposes.

(8) The authorisation for operation under Art. 8 (1) is issued within 15 days of inspection, if a favourable inspection report has been granted.

(9) In case of change of the holder of the community pharmacy authorisation under (1), the National Medicines Agency grants a new authorisation for operation in the name of the new owner within 30 days of request. Before issuance of the new authorisation, the community pharmacy operates under the former authorisation.

(10) Staff entitled to authorise or operate controls of community pharmacies or drugstores must be senior pharmacists and have at least 10 years experience in the specialty.

Art. 11. - (1) The current professional certificate of the College of Pharmacists in Romania is granted on request by the chief pharmacist.

(2) Any subsequent changes to the list of specialist staff is notified to the county branch of the College of Pharmacists in Romania and to the Ministry of Public Health within 30 days of the change.

Art. 12. - (1) The notice of opportunity is required before the establishment of community pharmacy and shall be issued within 15 days after filing for release by public health authorities within the area where establishment of the community pharmacy is required, provided the following are met:

a) in urban areas, a community pharmacy may be set up for a minimum of 3,000 inhabitants in Bucharest city and at least 3,500 inhabitants in county seat cities and at least 4,000 inhabitants in the other cities;

b) in rural areas, a community pharmacy may set up for a minimum of 4,000 inhabitants in localities over 4,000 inhabitants and no more than one pharmacy in localities under 4,000 inhabitants.

(2) By way of derogation from provisions in (1), one community pharmacy may also be established in railway stations and airports as well as in commercial centres with a minimum sales area of at least 3000 square meters provided for retail and catering activities, which are located in a single building using a common infrastructure and adequate utilities.

(3) It is the obligation of the Ministry of Public Health and of public health authorities to publish on their own websites the lists of their county localities where community pharmacies may be opened in accordance with conditions specified in (1) as well as lists of applicants for an opinion of opportunity, in filing order, specifying their submission date.

Art. 13. - (1) Companies that have established community pharmacies may establish one local distribution dispensary in localities lacking pharmaceutical services.

(2) The authorisation for operation of local distribution dispensaries is specified in the authorisation for operation of the holding community pharmacy.

(3) The community local distribution dispensary and the rural pharmacy operate in the presence of the pharmacist working according to their competences and operating hours established and publicly announced and communicated to the county branch of the College of Pharmacists in Romania.

(4) Where a community pharmacy is set up in the respective locality, the existing local distribution dispensary is discontinued.

SECTION 2

Organisation and operation of the community pharmacy

Art. 14. - (1) The community pharmacy is only located on the ground floor of buildings, provided with open and direct access from the street, except for community pharmacies located in shopping centres, railway stations and airports, to which access is also possible from inside their premises. Community pharmacies in healthcare units and shopping centres may be located no higher than their 1st floor.

(2) The premises of the community pharmacy have a minimum of 50 sqm usable area, outside hallways and bathrooms.

Art. 15. – The community pharmacy may only operate in the presence of at least one pharmacist in personal exercise of his profession, who may not be replaced by a person of any other profession.

Art. 16. - (1) Professional staff of the community pharmacy consists of:

- a) the chief pharmacist;
- b) pharmacists;

c) pharmacy assistants.

2) Under the supervision and control of a pharmacist entitled to free practice, students and resident pharmacists or other persons in pharmaceutical education process or professional training in higher pharmaceutical education institutions may also work in community pharmacies, to the extent of their competences.

(3) Pharmacy assistants aid pharmacists in their work, under their direct guidance.

(4) All persons involved in pharmaceutical activities in the community pharmacy must wear a badge bearing the person's full name, qualification and professional titles as well as the name of the community pharmacy.

(5) Any other personnel necessary for community pharmacy operation work under the control of the chief pharmacist.

Art. 17. - (1) The signboard of the community pharmacy company also includes the term "pharmacy" and, where appropriate, a name to distinguish it from other such establishments. The community pharmacy premises must be provided with a private area for discussions with patients, displayed in full sight. The community pharmacy premises not allowing, confidential discussions may take place in the office of the chief pharmacist.

(2) The distinctive sign on the emblem of the community pharmacy is the cross symbol with equal-sized, green on white sides, intersected at right angles.

(3) The display of the community pharmacy emblem and signboard are exempt from any fees.

Art. 18. - (1) The operating hours of the community pharmacy are established in accordance with the number of pharmacists employed under provisions of Title 14 of Law 95/2006 on healthcare reform, as amended.

(2) The manner of public pharmaceutical care provision during the night, weekends or holidays is established by the Ministry of Public Health and endorsed by the College of Pharmacists in Romania; this is binding for all community pharmacies under contract with health insurance houses.

(3) By way of exemption from provisions of (2), community pharmacies located in shopping centres work according to the operating hours of the latter.

Art. 19. – The organisation and operation of local distribution dispensaries are established by order of the minister of public health.

SECTION 3

Relocation of headquarters, transfer, interruption and termination of community pharmacy activity

Art. 20. - (1) Relocation of the headquarters of a community pharmacy is notified to the Ministry of Public Health and the College of Pharmacists in Romania.

(2) Start of operations at the new location is only possible provided conditions regarding authorisation are met and after the new location has been granted, according to this law, an authorisation for operation.

(3) Provisions under this Art. also apply to community pharmacies established according to Art. 12 (2).

Art. 21. - Relocation of headquarters is only allowed in the same locality. By December 31 2010, community pharmacies established under Art. 12 (2) may relocate under the same conditions only.

Art. 22. - (1) For sound reasons or for objective reasons expressed by the holder of the authorisation under Art. 10 (1), the Ministry of Public Health may approve interruption of community pharmacy activities for up to 180 days.

(2) The community pharmacy may voluntarily suspend its own activity for a period not exceeding 60 calendar days. If the suspension period exceeds 30 calendar days, notification of the Ministry of Public Health and the College of Pharmacists in Romania is mandatory.

Art. 23. – The community pharmacy stops its activity by cancellation of the authorisation for operation issued by the National Medicines Agency, under the following circumstances:

- a) on request by the holder of the authorisation for operation;
- b) dissolution of the trade company referred to in Art. 6. (1);
- c) withdrawal of the authorisation for operation;
- d) bankruptcy;
- e) interruption of activities for a period exceeding 180 days.

CHAPTER III

The drugstore

Art. 24. - (1) Companies whose object of activity is retail sale of pharmaceutical products may establish drugstores.

(2) The drugstore is headed by a chief pharmacist or a chief pharmacy assistant.

(3) Under (2), the position of chief pharmacist or chief pharmacy assistant may be held by pharmacists entitled to free practice, members of the

College of Pharmacists of Romania, namely pharmacy assistants entitled to free practice, members of the Order of Nurses and Midwives in Romania.

(4) The drugstore operates only in the presence of at least one pharmacy assistant or pharmacist.

Art. 25. - (1) The drugstore authorisation for operation is granted in the name of the legal body and the chief pharmacist or pharmacy assistant, as appropriate, by the Ministry of Public Health, through its Pharmaceutical Department.

(2) For grant of the authorisation for operation under (1), the Applicant shall submit the following documents:

- a) application form;
- b) the current professional certificate issued by the College of Pharmacists in Romania the chief pharmacist and the Order of Nurses and Midwives in Romania for pharmacy assistants, respectively;
- c) the set up documents of the company;
- d) a copy of the Applicant's certificate of registration in the Trade Register Office;
- e) the ascertaining certificate issued by the Trade Registry Office, indicating registration as a work area of the space for drugstore or, where applicable, of the registered activity office for which authorisation is sought;
- f) the blue print and data on unit premise, according to the order of the Minister of Health;
- g) the list of endowment with furniture, utensils and equipment, analysis table, according to the order of the minister of public health.

(3) The authorisation for operation under (1) is granted following a favourable inspection report provided by the Pharmaceutical Department within the Ministry of Public Health.

(4) In case of unfavourable inspection reports, a 45-day term is provided for remedy of deficits found.

(5) The authorisation for operation granted under this law includes the health authorisation for operation.

(6) The authorisation to operate under (1) is issued within 15 days of inspection, if a favourable report has been granted. Where the 15-day term is not observed, the drugstore is deemed to be authorised under the tacit approval procedure.

(7) In case of change of the holder of the drugstore authorisation under (1), the Ministry of Public Health grants a new authorisation for operation in the name of the new owner within 30 days of request. Before issuance of the new authorisation, the drugstore operates under the former authorisation.

Art. 26. - (1) The drugstore is located only on the ground floor of buildings in an area dedicated solely to drugstore business.

(2) The premises of the drugstore have a minimum of 30 sqm usable area, outside hallways and bathrooms and the office of the pharmacy assistant.

Art. 27. – Relocation of the drugstore properly applies provisions of Art. 20.

Art. 28. - (1) On force majeure grounds, the Ministry of Public Health may approve interruption of community pharmacy activities for up to 180 days.

2) The drugstore may voluntarily suspend its own activity for a period not exceeding 60 calendar days. If the suspension period exceeds 30 calendar days, notification of the Ministry of Public Health and the College of Pharmacists in Romania is mandatory.

Art. 29. – The drugstore stops its activity by cancellation of the authorisation for operation issued by the Ministry of Public Health under the following circumstances:

- a) on request by the holder of the authorisation for operation;
- b) dissolution of the trade company referred to in Art. 24 (1);
- c) the death of the holder/holders of the headquarters authorisation for set up;
- d) withdrawal of the authorisation for operation;
- e) interruption of activities for a period exceeding 180 days.

Art. 30. - The terms of drugstore organisation and operation are established by order of the minister of public health.

Art. 31. - (1) Drugstores may not use community pharmacy signs.

(2) The signboard of the drugstore includes the term “drugstore” only, followed by a name to distinguish it from other such units belonging to other legal entities.

(3) The name of the drugstore may not use the term "pharmacy", a derivative or abbreviation thereof.

CHAPTER IV

Supervision and inspection

Art. 32. - (1) Supervision and inspection of community pharmacies and drugstores may be exercised by the National Medicines Agency.

(2) Inspection is performed together with representatives of the College of Pharmacists in Romania, according to a protocol.

Art. 33. - Inspection in community pharmacies and drugstores is performed at least every 2 years.

CHAPTER V

Responsibilities and sanctions

Art. 34. - Violation of the provisions of this law triggers, where appropriate, disciplinary, contraventional and civil liability.

Art. 35. – The following are deemed as contravention and are punishable by a 200 - 1,000 lei fine:

a) failure to comply with the community pharmacy or drugstore operation hours;

b) violation of legal provisions on pharmacy or drugstore signboards.

Art. 36. - The following are deemed as contravention and are punishable by a 500 - 1,500 lei fine:

a) obstruction of inspection bodies activities;

b) display in breach of regulations in the field of advertisements on medicinal products inside the community pharmacy or drugstore.

Art. 37. – Employment of specialised pharmaceutical personnel not entitled to free practice, except for pharmacists and pharmacy assistants in training, is deemed as offence punishable by a 2,000 - 10,000 lei fine.

Art. 38. - Should inspection bodies referred to in Art. 32 find repeated violations of provisions regarding organisation, endowment and operation of the community pharmacy or drugstore, they may request suspension of operation and closure of the unit until remedy thereof.

Art. 39. - The following are deemed as contravention and are punishable by a 10,000 - 20,000 lei fine and closure of the community pharmacy/drugstore:

a) operation of a community pharmacy or drugstores without an authorisation for operation issued by the National Medicines Agency or the Ministry of Public Health, as appropriate, without a favourable pharmaceutical inspection report, respectively;

b) possession or supply in drugstores of medicinal products whose possession and supply are prohibited in drugstores;

c) breach of provisions under Art. 15 and Art. 24 (4).

Art. 40. – Ascertaining of facts deemed as contravention and application of fines is performed by inspectors of the State Sanitary Inspectorate of the Ministry of Public Health.

Art. 41. - Provisions of Government Ordinance No. 2 / 2001 on legal regime of contraventions, approved as amended by Law No. 180/2002, as amended apply to contraventions mentioned in this law.

CHAPTER VI
Transitional and final provisions

Art. 42. - (1) Community pharmacies drugstores established before the entry into force of this law remain established and may continue the work.

(2) Within 3 years as of this Law entry into force, units provided under (1) have to re-authorise and register into the National Register of pharmacy records, the National Register of drugstores, respectively.

(3) New authorisations for operation issued for community pharmacies under (1) provide for rights in Art. 2 (1).

Art. 43. – Provisions of Art.s 10 (2). b), (3) and (4), and of Art. 12 shall apply until 31 December 2010 included.

Art. 44. - (1) Fees and amounts thereof under this law amount are established by government decision.

(2) Fees under (1) are revenues for the state budget.

Art. 45. - (1) This Law shall take effect 60 days after publication in the Official Gazette of Romania, Part I.

(2) On the date of this law entry into force, Order of the Minister of health and the family no. 626/2001 on approval of the Norms on establishment and authorisation of pharmaceutical units, and the conditions of their organisation and operation, published in the Official Gazette of Romania, Part I, No. 629 of October 8, 2001, as amended, as well as any contrary provisions is hereby repealed.

This law has been adopted by the Romanian Parliament, in observance of Art. 75 and Art. 76 (2) of the Romanian Constitution, republished.

PRESIDENT
OF THE CHAMBER OF DEPUTIES,
BOGDAN OLTEANU

PRESIDENT
OF THE SENATE,
DORU IOAN TĂRĂCILĂ

Bucharest, 7 November 2008.
No. 266.