

# CROATIAN NATIONAL PARLIAMENT

1711

On the basis of article 88. Constitution of Republic Croatia, I am making

## DECISION

### CONCERNING THE ISSUE OF LAW ON PHARMACY

I am issuing the Law on pharmacy, passed by the Croatian Parliament on its session dated 17 July, 2003.

Number: 01-081-03-2664/2

Zagreb, 23 July, 2003.

President of  
Republic Croatia  
**Stjepan Mesić**, signed

## LAW

### ON PHARMACY

#### I. GENERAL PROVISIONS

##### Article 1.

This Law sets out organisation and execution of pharmaceutical activities as a part of health activities of interest to Republic Croatia which is being carried out as public service by pharmacists under conditions and in the way that is prescribed by this Law.

#### II. PHARMACEUTICAL ACTIVITIES

##### Article 2.

Pharmaceutical activities ensure the supply and production of medicine and supply of medical products to the population, health institutions and other legal corporations and health employees who work in the private practice.

##### Article 3.

Under the term supply of medicine is considered the retail sale of medicine. The sale of medicine is carried out in the pharmacies and pharmaceutical depots and encompasses ordering, storing and issuing medicine on prescription and over the counter (OTC) as well as production and sale of the main and galenic preparations of tested quality.

Procedure and method for retail sale of medicine proposed by the Croatian Chamber of Pharmacists (further in the text: Chamber) will be determined by the Book of rules prescribed by the minister responsible for health.

#### Article 4.

Under the term supply of medical products is considered the retail sale of medical products and encompasses ordering, storing and issuing of medical products.

Procedure and sale method of medical products proposed by the Chamber will be determined by the Book of rules by the minister responsible for health.

#### Article 5.

Under the term pharmaceutical activities in the item 2 of this Law, besides supply with medicine and medical products are also included the following:

1. supply with homeopathic products,
2. supply with baby food and diet products,
3. supply with cosmetic and other products for health protection determined by the general act of the Chamber
4. consulting concerning the prescribing, that is correct application of medicine, medical, homeopathic and diet products.

#### Article 6.

In the performance of pharmaceutical activities, pharmacists in cooperation with other health employees, carry out pharmaceutical care in order to achieve better pharmacotherapeutic effects and promoting the rational use of medicines and medical products and actively participate in the prevention of illness and protection of health.

Pharmaceutical care covers:

- rationalisation of costs for certain therapeutic protocols,
- improvement of pharmacotherapeutic procedures and realisation of therapeutic objectives,
- monitoring, avoidance or decrease of medical side effects,
- avoiding interactions, therapeutic doubling or allergic occurrences,
- care over adherence to therapeutic protocols by patients,
- improvement of clinical cure effects, and
- carrying out protective measures for preservation and protection of health.

### III. FOUNDING AND ORGANISING PHARMACEUTICAL ACTIVITIES

#### Article 7.

Pharmaceutical activities are performed within the basic health network in accordance with special law.

Pharmaceutical activities are performed in the primary, secondary and tertiary level of health protection.

#### Article 8.

Pharmaceutical activities are carried out in:

- pharmacies,
- pharmaceutical depots.

A section of pharmaceutical activities is performed in:

- galenic laboratories,
- laboratories for checking the quality of galenic preparations and identification of medicinal matters.

#### Article 9.

The organisational forms of pharmaceutical activities are as follows:

- pharmacy in which pharmaceutical activities are carried out as a form of private practice,
- pharmacy as pharmaceutical unity in the pharmaceutical health institution
- hospital pharmacy,
- pharmaceutical depot in which pharmaceutical activities are carried out as private practice,
- pharmaceutical depot as a unit in pharmaceutical health institution,
- galenic laboratory as a unit in the pharmaceutical health institution,
- galenic laboratory as pharmaceutical health institution,
- laboratory for testing the quality of galenic preparations and identification of medicinal matters as a unit in the pharmaceutical health institution,
- laboratory for testing the quality of galenic preparations and identification of medicinal matter as pharmaceutical health institution.

A pharmaceutical institution has to have at least two pharmaceutical units or one pharmaceutical unit and a galenic laboratory or one pharmaceutical unit and a laboratory for testing galenic preparations and identification of medicinal matter, or only a galenic laboratory or only a laboratory for testing the quality of galenic preparations and identification of medicinal matter

Pharmacy and depot are founded for certain areas in accordance with the conditions, which in accordance with the previously acquired opinion of Croatian institute for health insurance and the Chamber, prescribes the minister responsible for health.

#### Article 10.

A hospital pharmacy ensures the supply of hospital institution with medicine and medical products and prepares galenic and main preparations required for execution of hospital activities.

#### Article 11.

In galenic laboratories are made galenic preparations for pharmacies and health institutions in accordance with procedures prescribed by valid pharmacopoeic and main regulations.

Procedure and method of preparation of galenic preparations are prescribed by the Rules of good production practice for galenic laboratory.

Rules for good production practice from the item 2 of this article passes the minister responsible for health on the proposal of the Chamber, .

Procedure and method of founding and conditions concerning the space, workers and medical technical equipment for galenic laboratory will be ordained by the book of rules is proposed by the Chamber and set by the minister responsible for health.

#### Article 12.

In the laboratories for inspecting the quality of galenic preparations and identification of medicinal matter the testing of medicinal matter and checking the quality of galenic preparations for pharmacies and for health institutions is carried out in accordance with valid pharmacopoeic and main regulations.

The procedure and method of quality testing of galenic preparations and identification of medicinal matter are prescribed by the rules of good laboratory practice for laboratories from the item 1 of this article.

Rules of good laboratory practice, from item 2 of this article, will be passed by the minister responsible for health following the proposal from the Chamber.

Procedure and method of founding and conditions concerning space, employees and medical-technical equipment for the laboratory from item 1 of this article will be prescribed by the book of rules by the minister responsible for health following the proposal by the Chamber.

#### Article 13.

Pharmacy, hospital pharmacy, pharmaceutical unit, galenic laboratory and laboratory for quality testing of galenic preparations and identification of medicinal matter have to have a manager.

The manager is responsible for legal and professional work in pharmacies, pharmaceutical unity, that is, laboratories from the item 1 of this article.

The manager of pharmacies, pharmaceutical unity, that is, laboratory has to be a pharmacist who fulfil conditions from the article 20 item 1 of this Law.

The person from item 1 of this article can manage only one pharmacy, one pharmaceutical unity or laboratory.

### IV. PHARMACEUTICAL UNIT LEASEHOLD

#### Article 14.

Pharmaceutical activities can be carried out in private practice by giving in tenure parts of medical health institutions whose founder is a county (further in the text: leased unit) to pharmacists who fulfil the conditions prescribed by the Law.

#### Article 15.

Leased unit is given to tenure to a pharmacist who is in the permanent working status with a pharmaceutical health institution from the article 14 of this Law and has been working in the leased unit for the last year at least.

Pharmacist from the item 1 of this article has to fulfil the conditions for renewal of private practice for health workers of post-graduated level of education prescribed by the special law.

#### Article 16.

If in the individual leased unit work two or more pharmacists, they contract the lease in the form of group practice and the joint contract for carrying out health protection with the Croatian institute for health insurance.

#### Article 17.

Special conditions and procedure for giving on lease the units are set by the Book of rules which after the previously acquired opinion of the Chamber passes the minister responsible for health.

In relation to contracting, validity, breach any other issue related to the contracting concerning the leasing of the unit that are not set by this Law or regulation from the item 1 of this article, the general rules of mandatory law.

### V. PHARMACEUTICAL WORKERS

#### Article 18

Pharmaceutical workers are health workers who have pharmaceutical education and render immediate pharmaceutical services and they are:

- pharmacists with licence for independent work,
- pharmacists specialists with licence for independent work

in carrying out the pharmaceutical activities also participate pharmaceutical technicians with the passed professional exam.

#### Article 19.

A pharmaceutical technician can work in the pharmaceutical branch only in the presence of the pharmacist, and in accordance with the scope of work for pharmaceutical technicians (he/she must not issue the medicine on prescription, medicine that contain narcotic drugs nor prepare main preparations that contain matter of strong or very strong effect).

#### Article 20.

General conditions for performing pharmaceutical activities are:

- diploma of the university in Republic Croatia for profession pharmacists or validated foreign diploma for completed appropriate university post graduate study,
- passed professional examination,
- citizenship of Republic Croatia,
- knowledge of Croatian language
- entry into the Chamber register, and
- licence for independent work.

As exception to sub-item 3 item 1 of this article the foreign nationals can perform pharmaceutical activities in Republic Croatia according to the regulations that govern the work of foreign nationals in Republic Croatia.

A special condition for performing pharmaceutical activities is the post-graduate study in the field of pharmacy.

A special condition for the responsible person in preparation of galenic preparations in the galenic laboratory is the specialisation in pharmaceutical technology and a responsible person in the laboratory for quality control of galenic preparation and identification of medicinal matters within the specialisation in testing and control of medicine.

#### Article 21.

Pharmacist can start with work in the pharmacy after enrolling into the register of pharmacists at the Chamber or acquiring licence for independent work.

Entry into the Chamber register is carried out on the basis of written request by the pharmacist that is in accordance with the conditions set in the item 20, item 1 sub-items 1,2,3,4 and 6, that is, item 2 of the same article of this Law.

Conditions and methods of entry, handling and content of the register are prescribed by the general act of the Chamber.

#### Article 22.

A pharmacist must not without prescription or medical documentation, prescribed by the article 30 item 1 of this Law, issue medicine that is approved to be issued only on prescription in accordance with the special law.

A pharmacist must not place the medicine on retail sale through the Internet.

#### Article 23.

A pharmacist on duty is obliged to issue only a medicine on prescription that has the insignia of emergency, that is, only the medicine on the basis of other medical document from the article 30 item 1 of this Law with the insignia of emergency.

#### Article 24.

During his/her work, the pharmacists will withhold the following:

- issue of the medicine or medicinal product for which he/she professionally evaluates that it could endanger the health of the user,
- issue of medicine or medicinal product in case of incorrect medical documentation,
- issue of medicine or medicinal product in case of threat or violent behaviour of the user.

#### Article 25.

In the execution of pharmaceutical activities pharmacists are obliged to honour the Codex of pharmaceutical ethics and deontology and Rules on good pharmaceutical practice (GPP) .

#### Article 26.

Everything that a pharmacist learns about the user, during execution of his/her pharmaceutical activities, and that is related to user's state of health, has to be kept as pharmaceutical secret and can be divulged, unless this is differently prescribed by a special law, only with the permission of the user, parents or caretaker for minors, and in case of his/her psychological incapability or death by the approval of a closer family member, caretaker or legal representative.

### VI. LICENCE FOR INDEPENDENT WORK AND PERMANENT PROFESSIONAL EDUCATION OF THE PHARMACIST

#### Article 27.

The right on independent work has the pharmacist who was issued the licence for independent work

Licence for independent work is given to pharmacist or withheld by the legal act of the body determined by the Chamber Statute.

Against the legal act from the item 2 of this article there is no appeal, but the legal procedure could be instigated.

The types of licence for independent work are: a licence for independent work as pharmacist and a licence for independent work as a pharmacist specialist.

Conditions for issuing a licence for independent work as a pharmacist is regulated by the general act of the Chamber.

#### Article 28.

Pharmacists have the right and obligation to improve professionally in order to maintain and update the quality of pharmaceutical activities.

Pharmacists are obliged to undergo every six years a test of expertise at the Chamber in order to renew the licence for independent work in the field of pharmaceutical activities.

Conditions for renewal of licence for independent work of a pharmacist are determined by the general act of the Chamber.

For the procedure of renewal and revocation of licence for independent work are applied the provisions of the article 27, items 2 and 3 of this Law.

#### Article 29.

Chamber can temporarily or permanently revoke from the pharmacist the licence for independent work

Licence is temporarily revoked up to the period of one year, that is, until the reasons for which the licence was taken away still exist.

Licence is taken away temporarily:

– if the pharmacist did not fulfil the conditions set by the Chamber for professional improvements in order to maintain and update the quality of health protection for the period until the conditions are met,

– if the pharmacist was, by the Chamber court decision, the legally valid decision of the regular court or the decision of some other body, temporarily forbidden the execution of pharmaceutical activities,

– if the pharmacist in his/her work acts in juxtaposition to the provisions of this Law, for the period until such behaviour is removed.

Licence is revoked permanently:

– if the pharmacist was, by the Chamber court, the legally valid court decision or the decision of some other body, permanently forbidden the execution of pharmaceutical activities.

## VII. MEDICAL DOCUMENTATION

### Article 30.

Medical documentation in pharmaceutical activities encompasses:

– records kept during the performance of pharmaceutical activities,

- medical documentation for prescribing and issue of medicine and medicinal products

Type, contents and method of record keeping, informing and saving the records in the pharmaceutical activities are prescribed by the minister responsible for health, after the proposal of the Chamber.

The method of prescribing, type and content of the prescription, assignment and medical documents of the user, on the basis of which, the pharmacist can prepare, that is, issue medicine or medical product and the procedure for issue will be prescribed in the book of rules, that is, proposed by the authorised chambers, and passed by the minister responsible for health.

## VIII. PROFESSIONAL SUPERVISION

### Article 31.

Chamber carries out professional supervision over the work of pharmacies, laboratories and pharmacists.

Professional supervision from the item 1 of this article is carried out in accordance with the general act passed by the Chamber with approval of the minister responsible for health.

## IX. CROATIAN CHAMBER OF PHARMACISTS

### Article 32.

Croatian chamber of pharmacists is an independent professional organisation with characteristics of a legal corporative entity and with public office authorisations.

Chamber within the scope of its activities represents the pharmacists in Republic Croatia and abroad.

### Article 33.

The pharmacists, who through the pharmaceutical activities, work in the area of Republic Croatia on the activities directly connected to the health protection, are obliged to enrol in the Chamber.

In the Chamber can also enrol other pharmacists with the passed professional examination.

#### Article 34.

Chamber carries out the following public office activities:

1. keeps the records of the pharmacists which perform pharmaceutical activities in Republic Croatia,
2. issues, renews and revokes licences for independent work,
3. keeps the register of the pharmacies, pharmaceutical depots, galenic laboratories and laboratories for checking the quality of galenic preparations and identification of medicinal matter
4. makes the list of cosmetic and other means of health protection which can be issued in the pharmacies,
5. performs professional supervision over the work of pharmaceutical employees.

#### Article 35.

Chamber carries out the following activities:

1. makes the Codex of pharmaceutical ethics and deontology,
2. makes the Rules of good pharmaceutical practice (GPP) in good faith,
3. monitors and supervises the execution of the rules on pharmaceutical ethics and deontology and good pharmaceutical practice in the pharmaceutical branch and undertakes appropriate measures in case of their breach,
4. gives expert opinions and participates in the preparation of regulations in the field of pharmaceutical activities,
5. gives the proposal for the plan of required personnel to the minister responsible for health,
6. participates in determination of standards and norms of pharmaceutical services,
7. offers the protection to the citizens in realisation of their rights concerning the quality, content and type of pharmaceutical service that is being given,
8. organises additional improvements for expansion of activities within the branch in regards to the new methods in pharmacy,
9. organises the permanent professional further education for pharmacists and undertakes the control of the expertise,
10. represents the interests of their members when signing contracts with the Croatian institute for health insurance and other insurance companies,
11. sets the method of advertising and promoting the title of the private practice,
12. determines the method for forming the prices of medicine and other items that are not the subject of negotiations with the Croatian institute for health insurance,
13. gives approval to the forming of prices and other items form the voluntary insurance that are set by the contracts with insurance companies,
14. gives preceding opinion on the act by the Croatian institute for health insurance which determines the method of execution of the plan and program of measures in health protection, forming the process in the health protection and other basis for the making contract with the health institutions and private health workers that comprise the network of health activities,
15. takes care of the legal aid to its members,
16. takes care of the material and other interests of its members,
17. coordinates relations between the members and participates in the resolving possible disputes
18. carries out other activities set down by the law.



#### Article 36.

Chamber bodies are: General Assembly, Chamber Council, Chamber Commissioner, regional councils, Disciplinary court of the Chamber and other bodies determined by the statute and other general acts of the Chamber.

Constitution, authorisation, composition, method of choice, rights and obligations of Chamber bodies are all determined by the statute and other general acts of the Chamber.

#### Article 37.

Chamber Assembly passes the statute with the approval of the minister responsible for health.

Statute sets out the organisation and the scope of Chamber, the rights and obligations of the members, the Chamber bodies, sources of financing, general acts, professional sectors, procedure for issue, renewal and revocation of licence for independent work, protection of the members' rights and other matters important to the pharmacy and the Chamber.

#### Article 38.

For the realisation of its objectives and tasks, the Chamber receives its funds:

- from enrolment,
- from membership fees,
- from donations,
- from other sources realised by the Chamber activities

From the state budget of Republic Croatia are ensured the funds for activities that the Chamber is carrying out on the basis of authorised public offices set by the provision in the article 34, item 5 of this Law.

### X. DISCIPLINARY RESPONSIBILITIES

#### Article 39.

Pharmacists - Chamber members are responsible for heavier or lighter infringements of their duties and pharmaceutical reputation before the disciplinary bodies of the Chamber, set by the statute.

A heavier infringement is every breach of duty, reputation and Codex of pharmaceutical ethics and deontology that carries heavy significance in relation to the endangerment of the patients, nature of the breached duty, the level of material damage and other consequences in relation to the circumstances under which the act was performed or omitted.

A lighter infringement is a breach of duty, reputation and Codex of pharmaceutical ethics or deontology that is of lesser significance.

The general act of the Chamber closer determines what is deemed heavier, that is, lighter infringement of duty, reputation and Codex of pharmaceutical ethics and deontology.

#### Article 40.

For the lighter infringements of duty and reputation of pharmaceutical profession, that is, Codex of pharmaceutical ethics and deontology are issued a reprimand and cash fine.

For the heavier infringements of duty and reputation of pharmaceutical profession, that is, Codex of pharmaceutical ethics and deontology are issued a reprimand that is published in the Chamber paper, a temporary revocation of the licence for independent work or permanent revocation of the licence for independent work.

For the infringements of duty and reputation of pharmaceutical profession, that is, Codex of pharmaceutical ethics and deontology can be issued a measure of additional obligatory further professional education.

#### Article 41.

Cash fine can be set for lighter infringement in the amount of 1.000,00 to 2.000,00 kunas, and for heavier infringement from 3.000,00 to 5.000,00 kunas.

#### Article 42.

Disciplinary procedure is started by the disciplinary body set by the statute, in pursuance of its duty or on request by the Chamber body set by the general act of the Chamber or on request by the minister responsible for health.

#### Article 43.

In the disciplinary procedure against the pharmacists - the member of the Chamber are applied in an appropriate manner the provisions of the criminal material and procedural legislation.

#### Article 44.

The valid decision by the disciplinary body of the Chamber ordering cash fines are valid documents and the Chamber is authorised to request the coercive execution.

#### Article 45.

Against the second level decision in which is issued a disciplinary measure of temporary or permanent revoking of licence for independent work, the appeal to the Administrative Court of Republic Croatia is permitted.

#### Article 46.

Instituting procedure becomes the subject of statute of limitations in the period of one year from the cognition of the infringements by the body determined by the Chamber, that is in the period of two years from the deed itself.

The subject of statute of limitations for conduct of procedure starts in the period of three years from the initiation of the procedure. The statute of limitations are stopped by any processing action that is being taken for the conduct of the process.

The subject of statute of limitations for imposing the punishment, that is, the measure itself comes into force when two years have passed from the final decision by which that punishment, that is, the measure was imposed. The statute of limitations are stopped by each action taken for instituting the punishment, that is, the measure.

Instituting and conducting procedure for the infringements that have the characteristics of criminal acts have the statute of limitations in accordance with the regulation of the criminal material law.

### XI. SUPERVISION OF THE WORK OF THE CHAMBER

#### Article 47.

Supervision over the legality of the work of Chamber, in carrying out its public office duties, is performed by the ministry responsible for health.

For the supervision from the paragraph 1 of this article the ministry responsible for health may request appropriate reports and data.

Reports and data from paragraph 2 of this article, the Chamber is obliged to give to the ministry responsible for health within 30 days or in the same period inform it about the reasons for which it is unable to deliver the same.

Chamber is obliged to give to the minister responsible for health until 1<sup>st</sup> of March, an annual report concerning the work of public office duties for the preceding year.

## XII. ARBITRATION

### Article 48.

Pharmacists - members of the Chamber, that is, pharmacies can pass the solution of their mutual disputes concerning their activities to the Chamber for arbitration.

Nominating of arbiter or arbitration council and other issues of the arbitration procedures are set by the general act of the Chamber.

### Article 49.

In the agreement for placing the dispute before arbitration, the parties in the dispute will determine the point to be presented for the arbitration.

Arbitration may make a decision only on the point that was placed before it by the disputing parties.

### Article 50.

Decision of arbitration concerning disputed request is for the disputing parties a valid verdict of the regular court.

Decision of arbitration can be contested by the court in accordance with the special law.

## XIII. PENAL PROVISIONS

### Article 51.

With the cash fine in the amount from 20.000,00 to 80.000,00 kunas will be fined the legal corporative entity for the offence:

1. if in the legal transactions works under the name of pharmacy or pharmaceutical depot and does not carry out pharmaceutical activities (article 8 item 1),
2. if the medicine is placed for retail sale on the Internet (article 22 item 2).

For offence from item 1 of this article a physical person will be fined in the amount from 5.000,00 to 10.000,00 kunas.

### Article 52.

With the cash fine in the amount from 5.000,00 to 10.000,00 kunas will be fined for the offence the pharmacist with the licence for carrying out pharmaceutical activities in private practice, the head of the pharmaceutical institution and the head of the hospital institution if the pharmacy has no manager or if the manager does not fulfil the conditions from the article 20 item 1 of this Law (article 13 item 1 and article 20 item 1).

### Article 53.

With the cash fine in the amount from 5.000,00 to 10.000,00 kunas will be fined for the offence the pharmacist if:

1. he/she carries out the pharmaceutical activities outside the basic network in the field of health (article 7 item 1),
2. he/she carries out the work of a manager in several pharmacies, pharmaceutical units or laboratories (article 13 item 4.),
3. he/she starts independent work as a pharmacist in the pharmaceutical activities and does not have the licence for independent work (article 21 item 1.),
4. he/she without prescription or medical documentation prescribed by the provisions in article 30 item 1 of this Law issues the medicine that has approval for being placed for sale on prescription according to the special law (article 22 item 1.),
5. if he/she does not enrol into the Chamber but by carrying out on pharmaceutical

activities works directly in the region of Republic Croatia on the health protection activities (article 33 item 1).

Article 54.

With cash fine in the amount from 5.000,00 to 10.000,00 kunas will be fined the pharmaceutical technician if he/she participates in carrying out pharmaceutical activities in juxtaposition to provision of article 19 of this Law.

Article 55.

Who in juxtaposition to provisions of this Law carries out pharmaceutical activities will be fined by cash fine of one hundred and fifty daily wages or by penalty of up to 6 months imprisonment.

Who performs the criminal act from the item 1 of this article and for this receives a price or profit will be punished by cash fine of one hundred and fifty daily wages or by penalty of one year imprisonment.

#### XIV. TRANSITIVE AND FINAL PROVISIONS

Article 56.

Following the passing of this Law, Croatian chamber of pharmacists founded on the basis of the Law on health protection (Official Gazette, no. 75/93., 11/94., 55/96., 1/97. – final text, 111/97., 95/00. and 129/00.), continues to work.

Article 57.

Chamber is obliged to coordinate its Statute with this Law in the period of 6 months from the day this Law coming into force.

Other general acts the Chamber is obliged to coordinate with this Law and the Statute in the period of 12 months from the date of this Law coming into force.

Chamber is obliged to pass general acts set by this Law in the period of 6 months from the day of this Law coming into force.

Article 58.

Book of rules, for whose passing is authorised by this Law by the minister responsible for health, will be passed in the period of 6 months from the day this Law coming into force.

Article 59.

Until the day that the Book of rules from article 17 item 1 of this law is passed, the Book of rules concerning the leasing of health institutions of primary health insurance and sanatoriums is being applied (Official Gazette, no. 6/96. 29/97., 1/98., 45/99., 121/99., 112/00., 87/02., 150/02. and 7/03.) in the part that deals with the pharmacies.

Article 60.

Actions at the Ministry of Health and before the bodies of the Chamber which are in the procedure during this Law coming into force will continue according to the provisions, that is, acts according to which the procedure has been started.

Article 61.

This Law comes into force on the eight day from the day of announcement in the Official Gazette.

Class: 510-11/03-01/01  
Zagreb, 17 July 2003.

CROATIAN PARLIAMENT

President of

Croatian parliament

**Zlatko Tomčić**, signed.