National Training Requirements

LITHUANIA

Specialty

Clinical Pharmacology

(Klinikinė Farmakologija)

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LITHUANIAN MEDICAL NORM MN 158: 2016

DOCTOR CLINICAL PHARMACOLOGY. RIGHTS, DUTIES, COMPETENCE AND RESPONSIBILITY

CHAPTER I
SCOPE OF APPLICATION

1. This Lithuanian medical norm establishes the scope, rights, duties, competences and responsibilities of the physician's clinical pharmacologist.

2. This Lithuanian medical norm is obligatory for all doctors and clinical pharmacologists working in the Republic of Lithuania, their employers, as well as institutions preparing these specialists, who improve their qualifications and supervise their activities.

CHAPTER II
REFERENCES

3. In preparing this Lithuanian medical norm, the following legal acts are followed:

3.1. the Law on the Health System of the Republic of Lithuania;

3.2. the Republic of Lithuania Law on Health Insurance;

3.3. the Republic of Lithuania Law on Medical Practice;

3.4. the Law on Health Care Institutions of the Republic of Lithuania;

3.5. the Republic of Lithuania Law on Determination of Human Disease and Emergency Situations;

3.6. the Republic of Lithuania Law on Patients' Rights and Damages to Health;

3.7. the Law on Pharmacy of the Republic of Lithuania;

3.8. the Republic of Lithuania Law on Biomedical Research Ethics;

3.9. the Government of the Republic of Lithuania in 2003. October 31 Resolution No. 1359 "On the training of doctors";

3.10. Lithuanian Minister of Health in 2000. November 9 Order No. 634 "On Approval of General Requirements for the Formulation of Medical Standards";

3.11. Lithuanian Minister of Health in 2002. January 28 Order No. 58 "On the Procedure for Examination of the Professional Competence of Healthcare Professionals";

3.12. Lithuanian Minister of Health, Republic of Lithuania Minister of the Interior, the Prosecutor General of Lithuania in 2002. January 28 Order No 55/42/16 "On the provision of information on persons with bodily harm which may be related to a crime";

3.13. Lithuanian Minister of Health in 2002. March 18 Order No. 132 "On the Improvement of the Professional Qualifications of Healthcare and Pharmacy Specialists and the Procedure for Financing of the Health Care and Pharmacy Specialists";

3.14. Lithuanian Minister of Health in 2004. April 8 Order No. V-208 "On Approval of the Procedure and Scope of the Provision of Mandatory Medical Aid and Emergency Medical Aid Services";

3.15. Lithuanian Minister of Health in 2004. May 27th Order No. V-396 "On the Approval of the Rules for the Licensing of Medical Practice";

3.16. Lithuanian Minister of Health in 2004. June 28 Order No. V-469 "On Approval of the List of Types of Professional Qualifications for Medical Practice";

3.17. Minister of Health of the Republic of Lithuania and the Minister of Social Security and Labour of the Republic of Lithuania in 2005 June 30 Order No. V-533 / A1-189 "On Approval of Legislation Regarding Electronic Certificate of Incapacity for Work and Electronic Gestational and Maternity Leave";

3.18. Minister of Health of the Republic of Lithuania in 2005 October 27 Order No. V-820 "On the Approval of the Description of the Requirements for the Provision of Sepsis Hospital Services in Personal Healthcare Institutions";

3.19. Minister of Health of the Republic of Lithuania in 2008 June 28 Order No. V-636 "On Approval of the Procedure for Issuance, Dissemination and Answers for Sending Personal Health Care Services";

3.20. Minister of Health of the Republic of Lithuania in 2010 May 3rd Order No. V-383 "On Approval of the Procedure for the Use of Medical Devices (Instruments)";

3.21. Ministry of Health of the Republic of Lithuania, 2011 February 23 Order No. V-164 "On the Establishment of the Tenth Revision and Supplement to the International Standard Statistical Classification of Diseases and Related Health Problems", Systematic disease list of diseases (Australian Modification, ICD-10-AM) ";

3.22. Minister of Health of the Republic of Lithuania in 2013 February 20 Order No. V-185 "On the description of the procedure for submitting a suspected adverse reaction (SAR) by a health or pharmaceutical specialist, a form of approval of the form of a suspected adverse reaction (SAR) by a medical or pharmaceutical specialist, and a patient's report of a suspected adverse reaction (SAR)".

CHAPTER III
TERMS AND DEFINITIONS

4. Terms and definitions used in this Lithuanian medical norm:

4.1. **Clinical pharmacology** – a branch of biomedical sciences that includes the discovery and development of medicines, the use of drugs as a therapeutic tool, and all aspects of drug exposure to humans.

4.2. **Clinical pharmacologist** – the medical doctor, having obtained the professional qualification as clinical pharmacologist in accordance with the procedure established by legal acts.

4.3. **Practice of the clinical pharmacologist** – the legislation regulates the personal health care provided by the clinical pharmacologist of the clinic in accordance with the acquired professional qualifications and the established competence.

4.4. **Rational drug use** – the use of drugs when the patient is given the optimal treatment period at the appropriate time for the treatment of the most appropriate medical conditions and the cost of treatment is minimal for both the patient and the general public.

4.5. Other terms used in this Lithuanian medical norm shall be understood as defined in the legal acts specified in Paragraph 3 of this Lithuanian Medical Standard.

CHAPTER IV
GENERAL PROVISIONS

5. The professional qualifications of a clinical pharmacologist shall be obtained after completion of university medical studies and clinical pharmacology residency. The professional

qualification of a doctor as a clinical pharmacologist acquired abroad is recognized in accordance with the procedure established by legal acts of the Republic of Lithuania.

6. The right to practice clinical pharmacology in the Republic of Lithuania have individuals who have acquired the qualification as clinical pharmacologists in accordance with the procedure established by the legal acts of the Republic of Lithuania and who hold a medical practice license issued in accordance with the procedure established by the Republic of Lithuania in accordance with the procedure of medical practice of a pharmacologist.

7. To practice clinical pharmacology as specialist in clinical pharmacology in the Republic of Lithuania can only be done with a personal healthcare license to engage in personal health care and to provide clinical pharmacology services and/or other personal health care services, which according to the requirements of the law must also be provided by a clinical pharmacologist together with other healthcare professionals. The clinical pharmacologist provides services to patients of all ages.

8. The Clinical Pharmacologist is working independently in collaboration with other personal and public health care professionals.

9. The clinical pharmacologist in his work follows the laws of the Republic of Lithuania, this Lithuanian medical norm, statutes (regulations) of the institution in which he is employed, the internal rules of procedure, the description of his/her job and other legal acts.

CHAPTER V
RIGHTS

10. A clinical pharmacologist has the right to:

10.1. practice clinical pharmacology in accordance with this Lithuanian medical norm and other legal acts;

10.2 in accordance with the competence specified in section VII of this Lithuanian medical norm, to write prescriptions in accordance with the procedure established by legal acts of the Republic of Lithuania;

10.3 in accordance with the competence specified in section VII of this Lithuanian medical norm, to issue personal health certificates in accordance with the procedure established by legal acts of the Republic of Lithuania;

10.4 to advise patients and other medical specialists in the field of clinical pharmacology in accordance with the procedure established by legal acts of the Republic of Lithuania;

10.5 to advise patients and doctors to collaborate with other doctors and take their recommendations into account;

10.6 to refuse to provide personal health care services if this is contrary to the principles of professional ethics of the doctor or may pose a real danger to the life of the patient or doctor, except for the provision of emergency medical care;

10.7. to determine the fact of the death of a person in accordance with the procedure established by legal acts of the Republic of Lithuania;

10.8. to receive the necessary information about the patients, facilities, equipment, medicines in accordance with the procedure established by legal acts of the Republic of Lithuania;

10.9. by his/her competence to submit proposals to the administration of health care institutions, employers, the Ministry of Health of the Republic of Lithuania regarding working conditions, patient research, treatment, improvement of prevention of illness and health disorders and rational use of medicines;

10.10 by his/her competence to participate in meetings, conferences, various diagnostic, treatment and prevention programs, research and teaching activities, in the development and implementation of new medical and pharmaceutical technologies;

10.11 to be member of Lithuanian and/or foreign associations of clinical pharmacology, to participate in their activities;

10.12 to improve professional qualification in accordance with the procedure established by legal acts of the Republic of Lithuania.

11. The clinical pharmacologist also has other rights established by the legal acts of the Republic of Lithuania.

CHAPTER VI
DUTIES

12. The clinical pharmacologist must:

12.1. provide necessary medical assistance;

12.2. have a medical doctor's seal, the number of which has been given in accordance with the legal acts;

12.3. independently diagnose illnesses, treat patients, recommend preventive measures and ensure the quality of provided health care services in accordance with the competence specified in section VII of this Lithuanian Medical Standard;

12.4. cooperate with other personal and public health, nursing and social workers and specialists;

12.5. apply methods of research, diagnosis and treatment in Lithuania;

12.6. use only medical devices (appliances) that meet the requirements of the law, except for the exceptions provided by other legal acts. Ensure that medical tools (devices) are used in accordance with the legislation and in accordance with the information provided by the manufacturer with the medical tool (device);

12.7. promoting healthy lifestyles, measures to prevent and strengthen disease prevention and health;

12.8. in the absence of a clinical pharmacologist's competence, to send a patient to consult and treat a specialist in the particular field in accordance with the procedure established by legal acts;

12.9. carry out compulsory health programs;

12.10. observe the professional ethics of a doctor, respect and not violate patients' rights;

12.11. continuously improve professional qualifications in accordance with the procedure established by legal acts of the Republic of Lithuania;

12.12. handle medical documents in accordance with the procedure established by legal acts of the Republic of Lithuania;

12.13. explain the circumstances of the practice of the clinical pharmacologist at the request of the Ministry of Health and law enforcement agencies;

12.14. provide statistics, compulsory reporting data and other information in accordance with the procedure established by legal acts of the Republic of Lithuania;

12.15. to inform law enforcement authorities of all cases when a person whose life is threatened by bodily injuries applies to or is brought to the health care institution, as well as a person who is not in danger of life but who has been subjected to bruises, slicing, shooting;

12.16. perform other duties prescribed by legal acts of the Republic of Lithuania.

CHAPTER VII
COMPETENCE

13. The professional competence of the clinical pharmacologist consists of the knowledge, know-how, abilities and skills that he/she acquires after completing the

qualifications of the doctor of clinical pharmacology by continuing to improve his/her professional qualifications, taking into account the continuous progress of science and practice.

14. The clinical pharmacologist must know:

14.1. the basis of the organization of health care and social assistance;

14.2. the basis of health law;

14.3. working with documents and the basics of writing;

14.4. the basis of medical statistics;

14.5. the basic principles and types of health insurance;

14.6. the use of information databases;

14.7. the key health indicators;

14.8. the peculiarities of anatomy, physiology and pathophysiology of different age groups;

14.9 pharmacovigilance and risk management guidelines and principles for the conduct of clinical trials.

15. The clinical pharmacologist must be aware of:

15.1. bioethics and deontology;

15.2. clinical pharmacovigilance principles;

15.3. risk factors, causes, pathogenesis, symptomatology as well as diagnostic and treatment principles, drug indications and contraindications, prophylactic principles for diseases and disorders;

15.4. general and clinical pharmacology of drugs: pharmacodynamics, pharmaco-kinetics, pharmacogenetics and their effect on the desired and undesirable effects of drugs and drug interactions;

15.5. basics of pharmacoepidemiology and pharmacoeconomics;

15.6. rational use of medicines;

15.7. the principles of the benefits and risks of medicinal products;

15.8. pharmacovigilance and risk minimization principles.

16. The clinical pharmacologist must be able:

16.1. to provide medical treatment and make recommendations for the establishment of a general treatment plan;

16.2. to evaluate the compliance of the prescribed treatment with the principles of rational use of medicines;

16.3. to select the dose or adjust the dose based on the patient's age, gender, race, miscellaneous organ failures and drug or drug-to-food interactions;

16.4. interpret the indicators for the concentration of medicinal products in the blood and, if necessary, make recommendations for changing the dosage of the medicine;

16.5. to diagnose or predict clinically relevant drug interactions and manage them;

16.6. alone or together with other specialist doctors to diagnose and treat adverse drug reactions from the following medicines (codes according to the 10th edition of the International Standard Statistical Classification of Diseases and Related Health Problems (Australian Modification, ICD-10-AM)):

16.6.1. systemic antibiotics (Y40);

16.6.2. other systemic antimicrobial and antiparasitic drugs (Y41);

16.6.3. hormones, their synthetic substitutes and antagonists, not elsewhere classified (Y42);

16.6.4. anti-allergic and antiemetic drugs (Y43.0);

16.6.5. preparations primarily affecting blood components (Y44);

16.6.6. analgesics, antipyretics and anti-inflammatory medicines (Y45);

16.6.7. antiepileptic and antiparkinson drugs (Y46);

16.6.8. tranquilising (sedative) and hypnotic medicines (Y47);

16.6.9. anaesthetics and gas used for treatment (Y48);

16.6.10. psychotropic drugs not elsewhere classified (Y49);

16.6.11. central nervous system stimulants not classified elsewhere (Y50);

16.6.12. medicines primarily acting on the autonomic nervous system (Y51);

16.6.13. medicines primarily acting on the cardiovascular system (Y52);

16.6.14. medicines primarily acting on the digestive system (Y53);

16.6.15. medicines primarily affecting water balance, mineral metabolism and uric acid metabolism (Y54);

16.6.16. medicines primarily affecting the smooth muscle and muscle of the skeletal system and the respiratory system (Y55);

16.6.17. topic (local) substances primarily affecting the skin and mucous membranes, as well as medicines used in ophthalmology, otorhinolaryngology and dentistry (Y56);

16.6.18. other and unspecified products (Y57);

16.6.19. bacterial vaccines (Y58);

16.6.20. other and unspecified vaccines and biological substances (Y59);

16.7. taking into account the patient's condition and the properties of the medicine, to devise measures to reduce the risk of drug-induced adverse reactions;

16.8. diagnose and treat overdosing with medicines:

16.8.1. systemic antibiotic poisoning (T36);

16.8.2. poisoning with other anti-infectious and antiparasitic drugs (T37);

16.8.3. poisoning with hormones and their synthetic substitutes and antagonists, not classified elsewhere (T38);

16.8.4. Non-opioid analgesics, antipyretics and anti-tumour drugs (T39);

16.8.5. poisoning with narcotics and psychedelics (hallucinogenics) (T40);

16.8.6. poisoning with anaesthetic and medical gas (T41);

16.8.7. poisoning with antiepileptic, sedative, hypnotic and antiparkinson medicines (T42);

16.8.8. poisoning with psychotropics, not elsewhere classified (T43);

16.8.9. poisoning with medicines acting on the vegetative (autonomic) nervous system (T44);

16.8.10. systemic and hematologic toxicity not classified elsewhere (T45);

16.8.11. cardiovascular toxicity (T46);

16.8.12. poisoning with preparations for the digestive system (T47);

16.8.13. poisoning with preparations that affect the smooth and skeletal muscles and the respiratory system (T48);

16.8.14. poisoning with topical preparations for the treatment of skin and mucous membranes, as well as preparations used in ophthalmology, otorhinolaryngology and dentistry (T49);

16.8.15. diuretic and other unspecified medicines, preparations and biological substances (T50);

16.9. to diagnose the ineffectiveness of medication treatment, to evaluate possible causes and, if necessary, to recommend alternative treatment;

16.10. to diagnose drug abuse;

16.11. to diagnose drug dependence.

17. The clinical pharmacologist must be able to:

17.1. counsel patients and healthcare professionals on all issues related to drug use;

17.2. plan and conduct clinical trials:

17.2.1. prepare a plan for the execution of a clinical trial and other documents necessary for carrying out a clinical trial;

17.2.2. independently organise and carry out observational (first and second phase of clinical trials), bioequivalence clinical trials, pharmacoeconomic and pharmaco-epidemiological studies;

17.2.3. counsel doctors of other specialties on clinical trials;
17.2.4. interpret the results of clinical trials;
17.3. evaluate the benefits and risks of medicinal products;
17.4. carry out pharmacovigilance activities:
17.4.1. analyse reports of adverse drug reactions and evaluate causation;
17.4.2. propose risk mitigation measures for adverse drug reactions;
17.4.3. counsel doctors of other specialties on pharmacovigilance issues;
17.5. carry out activities that promote the rational use of medicines.

CHAPTER VI
RESPONSIBILITY

18. The clinical pharmacologist is responsible for clinical mistakes, negligence, inappropriate fulfilment of functions assigned to him or violation of bioethical requirements, as well as for exceeding the competence in accordance with the procedure established by legal acts of the Republic of Lithuania.

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