VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

REGULATION
on the education, rights and obligations of pharmacists and criteria for granting of licences and specialist licences, No. 1090/2012.

SECTION I
General provisions.
Article 1
Scope.

This Regulation applies to pharmacists holding licences and specialist licences from the Medical Director of Health under Articles 2 and 5.

SECTION II
Licences.
Article 2
Professional title.

The right to use the professional title of pharmacist and to practise as such in Iceland is confined to those who have been granted a licence by the Medical Director of Health.

Article 3
Criteria for granting of a licence.

A licence under Article 2 may be granted to those who have completed an MA degree in pharmacy from the Faculty of Pharmaceutical Sciences in the University of Iceland's School of Health Sciences, and in addition six months' practical training in a pharmacy or hospital dispensary.

A licence from a state within the European Economic Area (EEA) and Switzerland may also be confirmed, or a licence issued on the basis of education in those states. Recognition of professional qualifications and competence of a pharmacist who meets the criteria of Directive 2005/36/EC, on the recognition of professional qualifications, with subsequent amendments, is subject to Regulation on recognition of professional qualifications and competence of healthcare practitioners from other EEA states, No. 461/2011, or to Nordic Convention on a common Nordic labour market for certain health professionals and veterinarians, No. 36/1993 (*cf.* Amendment No. 6/2001).

A licence may also be granted to those who have completed a comparable qualification from an educational institution in a state outside the EEA or Switzerland, which is recognised as such by Icelandic health authorities, and by health authorities in the state where the education took place.

Other criteria for the issue of a licence are subject to Article 12.

Article 4
Opinions.

Before a licence is granted under Article 2 on the basis of education outside Iceland under the third paragraph of Article 3, the Medical Director of Health shall elicit the opinion of the Faculty of Pharmacy in the University of Iceland's School of Health Sciences, with regard to whether the applicant fulfils the criteria for education under the first paragraph of Article 3, for granting of a licence.

The Medical Director of Health may elicit opinions from other bodies, as deemed necessary.

SECTION III

Specialist licences in pharmacy.

Article 5

Specialist licences.

The right to use the title of specialist in pharmacy and to practise as such in Iceland is confined to those granted a licence by the Medical Director of Health.

Article 6

Criteria for specialist licences.

Specialist licences may be granted in specialist fields of pharmacy. This is subject to the condition that the specialist training of the applicant is defined as being within the specialist field for which he/she applies for a specialist licence. The relevant specialist field shall have a solid theoretical basis, and an equivalent shall exist in a recognised international forum.

In order to be entitled to receive a specialist licence under Article 5 a pharmacist shall fulfil the following standards:

1. he/she shall be licensed as a pharmacist in Iceland under Article 2; and
2. he/she shall have completed a master's or doctoral degree relevant to pharmacy or have equivalent education; and
3. he/she shall have worked as a pharmacist after graduation under indent 2 for the equivalent of at least two years full-time in the field for which the application for a specialist licence is made. If he/she has worked less than full-time, the duration of employment shall be proportionately longer.

Up to twelve months full-time may be subtracted if the person has been employed alongside doctoral studies in the relevant specialist field.

Further criteria for the granting of a specialist licence are subject to Article 12.

Article 7

Application and opinions.

An application for a specialist licence in pharmacy, together with documents confirming education and professional experience, and other necessary documents, shall be submitted to the Medical Director of Health.

Before a specialist licence is granted under Article 5 the Medical Director of Health shall elicit the opinion of the Faculty of Pharmacy in the University of Iceland's School of Health Sciences, with regard to whether the applicant fulfils the criteria of Article 6.

The Medical Director of Health may appoint a special committee to evaluate and comment upon applications for specialist licences.

The Medical Director of Health may elicit opinions from other bodies, as deemed necessary.

SECTION IV

Rights and obligations.

Article 8

Professional standards and responsibility.

A pharmacist shall show respect for the patient/client and perform his/her tasks vigilantly and conscientiously and in accordance with the professional standards required of the profession at any time.

A pharmacist must be aware of his/her duties and respect ethical rules of the profession, maintain his/her knowledge and professional skill, and master innovations in his/her field of work.

A pharmacist shall be familiar with legislation and regulations applying to healthcare practitioners and healthcare services, and other legislation and government directives, as applicable.

A pharmacist is responsible for handling medications and as applicable advice, diagnosis and resolution of medication-related problems of patients/clients.

A pharmacist shall recognise his/her professional limitations, and seek assistance or refer the patient to another healthcare practitioner as necessary, for instance if he/she judges that he/she cannot provide the patient with appropriate healthcare service.

Article 9

Duty to inform and keeping of medical records.

The duty of a pharmacist to provide information to a patient is subject to the provisions of the Patients' Rights Act, No. 74/1997.

The duty of a pharmacist to provide information to the Medical Director of Health, *inter alia* with respect to monitoring and for the purpose of producing health reports, is subject to the provisions of the Medical Director of Health and Public Health Act, No. 41/2007.

A pharmacist shall, as appropriate, enter medical records in accordance with the provisions of the Medical Records Act, No. 55/2009, and regulations issued on the basis of the Act.

Article 10

Assistants and trainees.

A pharmacist is responsible for assistants and trainees under his/her supervision having sufficient competence and knowledge, and receiving the necessary guidance and instructions, to carry out tasks which he/she allots to them.

Article 11

Confidentiality.

A pharmacist shall maintain the utmost confidentiality regarding anything of which he/she becomes aware in his/her work about a patient's health, condition, diagnosis, prognosis and treatment, and other personal information. This does not apply where other provisions are made by law, or where reasonable cause exists to breach confidentiality for reasons of urgent necessity.

A pharmacist can be released from the obligation of confidentiality by the consent of a patient, or guardian if applicable.

The duty of confidentiality under this Article does not apply to cases in which the pharmacist has a duty to report under other legal provisions. In such cases, the duty of the pharmacist is to notify the relevant authority.

A pharmacist's duty of confidentiality is also subject to the provisions of the Patients' Rights Act, the Medical Records Act and other legislation as applicable.

SECTION V

Various provisions.

Article 12

Further criteria for granting of licences and specialist licences.

An applicant for a licence as a pharmacist under Article 2 and a specialist licence in pharmacy under Article 5 who is from a state outside the EEA and Switzerland, with which Iceland has not made an agreement on recognition of professional qualifications and competence, shall submit *inter alia* documentary evidence of nationality, content and duration of education, in addition to an examination certificate, a licence if the profession is an authorised profession in the applicant's state of origin, intended employment in Iceland, and any other documents and certificates deemed by the Medical Director of Health to be necessary for the issue of a licence.

Before an application for a licence is evaluated, as applicable a certified copy must be submitted of an application for residence and work permits, together with a signed contract of employment.

A requirement may be made for knowledge of the Icelandic language and Icelandic healthcare legislation, and other legislation and government directives, as deemed necessary in the work of a pharmacist, especially with regard to patients' safety and communication with patients.

Should it not have been demonstrated, in the judgement of the Medical Director of Health, that the applicant's qualification fulfils the criteria under the first paragraph of Article 3 or Article 6, an applicant may be required to submit to a test of competence to demonstrate that he/she possesses the professional knowledge and competence required in a pharmacist, or a pharmacist holding a specialist licence. An appropriate educational institution shall organise this test for the applicant in consultation with the Medical Director of Health.

A licence and specialist licence is issued when the applicant commences work in Iceland.

Article 13

Fees.

Fees for the issue of a licence or specialist licence are subject to Article 10 of the Treasury Supplementary Revenues Act, No. 88/1991.

Fees for all administration undertaken by the Medical Director of Health with regard to applications for licences and specialist licences, in addition to the fee under the first paragraph, and for tests of professional knowledge and competence, are subject to Regulation on fees for applications for healthcare practitioners' licences and specialist licences, No. 951/2012.

Article 14

General provisions.

The provisions of the Healthcare Practitioners Act, No. 34/2012, the Medical Director of Health and Public Health Act, No. 41/2007, the Medical Records Act, No. 55/2009, the Health Service Act, No. 40/2007, the Patients' Rights Act, No. 74/1997, and other legislation and government directives apply to pharmacists as applicable.

Article 15

Entry into force.

This Regulation, issued on the basis of Articles 5, 8, 30 and 31 of the Healthcare Practitioners Act, No. 34/2012, takes effect on 1 January 2013. From that time Regulation on the granting of specialist licences to pharmacists, No. 449/1978, with subsequent amendments, is abrogated.

Ministry of Welfare, 11 December 2012.

Guðbjartur Hannesson.

Vilborg Ingólfsdóttir.

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