



Consultation Document:

Proposed changes to the Pharmaceutical Society of Ireland (Fees) Rules, Pharmaceutical Society of Ireland (Registration) Rules, and Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules necessitated by changes to Directive 2005/36/EC.

Context

The Professional Qualifications Directive ([Directive 2005/36/EC](#)) enables and facilitates the free movement of professionals, such as pharmacists, doctors etc., within the EU, by establishing a framework to facilitate the mutual recognition of professional qualifications. This applies in general to all regulated professions, unless otherwise stated and the particular profession is regulated by other specific directives e.g. lawyers, statutory auditors. The provisions of the Directive are implemented nationally as it pertains to pharmacists in the [Pharmacy Act 2007](#), and the PSI Registration Rules, with the PSI delegated as the Competent Authority (CA) in Ireland for the purposes of the Directive as it relates to pharmacists.

Background

Directive 2005/36/EC has been amended by [Directive 2013/55/EU](#) and [Implementing Regulation 2015/984](#). The amending provisions derived from 2013/55/EU are required to be implemented by 18 January 2016 in national legislation. Ireland has an obligation derived from its membership of the EU to make all required amendments to facilitate the working of the Directive, and the policy considerations derive from the European agenda.

Legislative Change Requirements

- The Pharmacy Act 2007 will require amendment to provide for the transposition of the amending Directive.
- Currently work is ongoing, led by the Department of Education, in drafting a Statutory Instrument (European Union (Recognition of Professional Qualifications) Regulations) under the European Communities Act (ECA), which will nationally implement the general provisions of Directive 2013/55/EU.

As a consequence of the Directive amendments, a number of PSI statutory rules require revision. These are the:

1. Pharmaceutical Society of Ireland (Registration) Rules 2008
2. Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014
3. Pharmaceutical Society of Ireland (Fees) Rules 2014.

A summary overview of the changes in relation to the three Rules and link to the proposed draft amending statutory instruments are provided below.

1. Pharmaceutical Society of Ireland (Registration) Rules 2008 (S.I. No. 494 of 2008)

Legislative change required: amendment of rules to provide for

- Part 7 to facilitate the recognition decision in respect of EU qualifications
- Schedule 1 is to be amended

Recognition of Qualification:

Currently, Section 14 of the Pharmacy Act 2007 deals with the criteria to be met when registering as a pharmacist, and Section 16 deals with the recognition of the qualification held as being a “qualification appropriate for practice”.

The current framework provided by the Act and the Regulations made thereunder, associate the processes of recognition and registration under one process structure in the case of EU obtained qualifications. It is necessary to clearly delineate and provide for the making of a recognition decision, and a registration decision, and the framework requires amendment, via a Rule change, to facilitate this.

Language Competence:

Section 14 of the Act already gives effect to two regimes regarding language competence for (1) nationals, and EU, and (2) non-nationals. The amending Directive clearly decouples the recognition and language competence criteria, and while a qualification may be recognised, language skills may be assessed subsequent to this by a host member state prior to facilitating access to the profession.

It is understood that an amendment of Section 14(1)(h) of the Act is being considered to the effect that an EU or national graduate will be required to satisfy the Council that he or she has the linguistic competence necessary to be a registered pharmacist in the State.

As a consequence, the PSI Registration Rules will then need to be subsequently amended to reflect what satisfies the PSI Council in respect of language competence.

2. Amendments to Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (SI No. 377 of 2014)

Legislative change required: Amending Rules are to be drafted to amend Rule 23(2) of SI 377 of 2014.

The Directive provides that Member States may, in national legislation, set a reasonable limit on the duration of the part of the professional traineeship that may be carried out abroad. The current national rules therefore allow that a third of training required by national legislation may be carried out in another EU member state.

Provision must be made to allow individuals who commenced training under the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 to avail of this.

3. Amendments to Pharmaceutical Society of Ireland (Fees) Rules 2014 (SI No. 378 of 2008)

Legislative change required: Amendment required to provide for fees to be levied by the PSI associated with the operation of the European Professional Card (EPC) system, and the associated measures needing to be put in place.

The principle of equitable fees is adhered to irrespective of whether an applicant uses the current paper system, or the new EPC system. No changes in the current, Ministerially approved PSI fee levels are proposed in this SI.

Proposed draft amending Rules

- [Draft PSI \(Registration\) \(Amendment\) Rules](#)
- [Draft PSI \(Fees\) \(Amendment\) Rules](#)
- [Draft PSI \(Education and Training\) \(Integrated Course\) Rules](#)

See existing [PSI statutory Rules](#) on the PSI website.

This document should be read in conjunction with the consultation notice on the PSI website during the consultation period in January 2016.

You can contact the PSI in relation to this topic by email to consultation@psi.ie or by post to PSI House, 15-19 Fenian Street, Dublin 2, D02 TD72. Please mark your submission as 'Professional Qualifications Directive'.