

Information Document

Chronology and Overview of PSI development of Rules on Temporary Absence

The [Pharmacy Act 2007](#), as amended, creates a framework whereby patients and members of the public can expect that a pharmacist will be available and practising within a pharmacy when they visit to have medicines dispensed or to obtain advice on a health or medicines matter.

It is an offence to operate a retail pharmacy business other than in accordance with particular conditions, one of which is that the sale and supply of medicinal products must be carried out by or under the personal supervision of a registered pharmacist at all times (Section 26). However, the Act provides for one exceptional circumstance and that is that no offence is committed where a registered pharmaceutical assistant acts on behalf of a registered pharmacist during the temporary absence of the registered pharmacist (Section 30).

The development of rules under the provisions of Section 30 of the Pharmacy Act 2007 has been actively under consideration by the Pharmaceutical Society of Ireland since October 2013.

In July 2014, the PSI issued by email and letter, a request for submissions from a random sample of pharmacists and pharmaceutical assistants on the PSI Registers, and a number of selected stakeholders including the Pharmaceutical Assistants Association. The purpose of this engagement was to obtain views from interested individuals and organisations in order to inform the development of policy and to identify possible approaches that could be incorporated into a legislative framework under Section 30(2) of the Pharmacy Act 2007 relating to the circumstances in which a registered pharmaceutical assistant may act in the temporary absence of a registered pharmacist in the conduct of a retail pharmacy business.

In 2016, the PSI consulted on the first set of draft rules. The rules were issued for consultation accompanied by an information note. The [Consultation report of submissions received on the draft Temporary Absence Rules 2016](#) is published on the PSI website as is the [background information](#) note issued. At its meeting in March 2017 the Council considered the feedback received from the public consultation, heard an address from the Chairperson of the Pharmaceutical Assistants Association, and cognisant of its regulatory remit decided to reject the proposal presented at that time. The Council directed further examination of the issue of temporary absence, and what would be covered within the scope of the rules.

A Working Group was then established to examine and produce a report. The considerations of the group were informed by an independent report from the National Recognition Information Centre for the UK (NARIC) on the Pharmaceutical Assistant qualification, and centred on patient safety, public protection and risk in proposing how long a pharmacist may be absent from a pharmacy. At their meeting on 17 May 2018, the Council considered the matter and accepted the [Working Group report](#) and its recommendations as the policy basis for the further development of rules. It was agreed to proceed with developing draft rules under section 30 of the Act, based on this proposed policy. New draft rules were considered and approved for consultation by the Council at the 21 June 2018 Council meeting, and a [public consultation](#) was carried out in July and August 2018 with the revised [draft rules](#).

At the meeting of the Council on 20 September 2018, the Council agreed that the proposed PSI (Temporary Absence of a Pharmacist from a Pharmacy) Rules 2018, without change, be submitted to the Minister for Health for his consent so that they might be made into law. Subsequently an issue arose which required the re-consideration of one specific rule. This arose in the context of an element of the drafting framework used in the rules, and it required that the tasks that might be undertaken during a pharmacist's period of temporary absence were to be incorporated within the Rules, rather than as envisaged under the Rule 8 proposal considered by the Council in September 2018.

A risk matrix had been drawn up as part of the Working Group report on temporary absence, for the Council's consideration. This matrix of tasks assisted in the development of the Rules published for consultation in December 2018, which will address in Rule 8 the activities that may be carried out by a pharmaceutical assistant when acting on behalf of a pharmacist, in their temporary absence. An expert group was also constituted and asked to critically assess on the basis of risk, patient safety and public protection the provision(s) contained within Rule 8 of the draft statutory rules which provides for what can be done by a pharmaceutical assistant during the temporary absence of a pharmacist, with such assessment having due regard to the principles of necessity, effectiveness, proportionality, transparency, accountability and consistency.

At the Council meeting on 6 December 2018, the revised draft Rules were considered, and approval was given for these to be issued for public consultation. The proposed rules define parameters around how long a pharmacist may be temporarily absent from a pharmacy, and what may be done by a registered pharmaceutical assistant acting on behalf of the pharmacist in his/her temporary absence. The proposed rules do not impose any limitations on what can be done by a registered pharmaceutical assistant when acting in his/her capacity as recognised in Section 31 of the Act in providing skilled assistance to a registered pharmacist.