PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Working Group on Temporary Absence Report

20th April 2018

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APPENDICES

Introduction

The Pharmaceutical Society of Ireland (PSI) is the pharmacy regulator with responsibility to safeguard public health and safety by regulating pharmacists and pharmacies.

The PSI is governed by a 21-member Council appointed by the Minister for Health. The work of the PSI is supported by Advisory Committees of the Council, as well as three Statutory Committees with responsibilities in relation to complaints and fitness to practise matters. An executive staff support the work of the Council under the leadership of the Registrar/CEO.

The Council is responsible for ensuring the delivery of the functions of the PSI. These include:

- registration of pharmacists and pharmacies;
- setting of standards for pharmacy education and training at undergraduate and postgraduate levels, including ensuring that all pharmacists are undertaking appropriate continuing professional development (CPD);
- quality assurance of standards in pharmacy practice and supporting the development of pharmacy practice for the benefit of patients and the wider health system;
- regulatory functions including inspection and enforcement, handling complaints and disciplinary matters, including the imposition of sanctions and taking prosecutions;

The PSI regulates the professional practice of approximately 5,900 pharmacists, 360 pharmaceutical assistants and 1,900 pharmacies. The PSI acts to protect and promote the health, safety and wellbeing of patients and the public.

The PSI is an independent statutory body established under the Pharmacy Act 2007 (the Act) and is an agency of the Department of Health. The being and function of the PSI is defined and outlined in the framework provided by the Act, with the manner in which it conducts its functions and duties further outlined in the rules made under the authority of the Act.

This report is focused on the development of rules under Section 30 of the Act which provides the following:

" 30.—(1) No offence is committed under section 26 where a registered pharmaceutical assistant acts on behalf of a registered pharmacist during the temporary absence of the registered pharmacist.

(2) Rules made by the Council with the consent of the Minister may, for the purposes of subsection (1), provide further as to—

(a) what may or may not be done by a registered pharmaceutical assistant when acting on behalf of a registered pharmacist,

(b) what constitutes the temporary absence of a registered pharmacist."

Background

Under the provisions of the Pharmacy Act 2007 (the Act) (as amended) a "pharmaceutical assistant" means "a person who before the coming into operation of section 4(1) of this Act was competent, under section 19 of the Pharmacy Act, (Ireland) Amendment Act 1890 to transact the business of a pharmacist in his or her temporary absence".

Under Section 19 of the Pharmacy Act, (Ireland) Amendment Act 1890 it was provided that " the Council may cause examinations to be held at such times and in such manner as may be prescribed by them from time to time for the purpose of examining assistants to pharmaceutical chemists and such assistants as shall pass such examination shall be competent to transact the business of a licentiate of the Pharmaceutical Society in his temporary absence but shall not be entitled to conduct or manage a business or to keep open shop on their own account." The old Pharmaceutical Society of Ireland was responsible for the conduct of such examinations. By virtue of section 30(1) of the Act, a person whose name is entered in the register of pharmaceutical assistants is permitted to act on behalf of a registered pharmacist during the temporary absence of the registered pharmacist.

The current understanding regarding scope of practice and what constitutes temporary absence is based on the Code of Practice governing the temporary absence clause of the Pharmacy Act (Amendment) Act 1890 as agreed with the Pharmaceutical Assistants Association following discussions that took place in 1994.

Education and Training

Since the inception of the qualification of "Pharmaceutical Assistant (PA)" in 1890, the training appears to have been delivered in two particular formats. Between 1890 and 1958, it is understood that no individual distinct course was provided for the PA qualification. Students registered to undertake the pharmaceutical licence course were also entitled on completion of that course to sit the "Examination for the Qualification of Assistant to Pharmaceutical Chemist". An individual who was not successful in the pharmaceutical licence examination could sit the PA examination and/or continue to repeat the pharmaceutical licence examination until successful. The then course of training was delivered on a primarily vocational basis with part time/evening academic attendance requirements prior to the student being eligible to sit either of the prescribed professional examinations. In this scenario it was conceivable, and in many cases a reality, that an individual could qualify as a PA and subsequently take the examination to qualify as a Registered Chemist.

Between 1950 and 1960, the training to become a pharmacist consisted of a five year course consisting of a "First Professional" academic year followed by three years apprenticeship in a pharmacy and a "Second Professional" academic year, the successful completion of which required the passing of the final pharmaceutical licence examination. The training to become a Registered Pharmaceutical Chemist from circa 1960 to 1977 consisted of a three year Academic degree undertaken at third level, followed by a one year practical training/apprenticeship position.

When the envisaged transfer of pharmacist education to University was imminent, the Council in 1958 decided to establish an independent parallel course leading to the qualification of an "Assistant to a Pharmaceutical Chemist". Between circa 1960 and 1982, an individual wishing to train as a PA, would after having achieved leaving certificate/matriculation level:

• serve an apprenticeship to a registered pharmaceutical chemist for a period of not less than three years, with formal notification to the old PSI, prior to the commencement of the period of tutelage and following its completion. Any changes to the tutelage placement would also have to be notified to the old PSI.

• On completion of this apprenticeship, the student was required to attend an academic course for a period of one academic year and was required to pass an examination, which included practical examinations in some subjects, as prescribed by the Pharmaceutical Society of Ireland. (Sample unattributed curriculum document located at Appendix Six)

On the current Register of Pharmaceutical Assistants the earliest qualification held by a PA dates from 1961. In 1979 the last persons to be examined as Pharmaceutical Assistants commenced the required practical training component. The last course of academic training delivered for Pharmaceutical Assistants under the meaning of Section 19 of the Pharmacy Act 1890 commenced in October 1982 with the last examination in this regard held in 1985.

A Preliminary/Apprenticeship Register and a Register of Pharmaceutical Assistants was maintained by the PSI at that time.

Temporary Absence Agreement of 1994

In 1994 the Council of the old PSI, together with the Executive Committee of the Pharmaceutical Assistants Association negotiated an Agreement and a draft Code of Practice governing Temporary Absence Clause to standardise interpretation of the provision ”temporary absence” , with the final meeting held between the PSI and the Pharmaceutical Assistants Association (PAA) on the 4th August 1994 . The agreement between the old PSI and the PAA sought to set out a mutual understanding of what the 1890 Act provided for, and was a statement of intent as to how the two parties considered “temporary absence” should be understood.

In summary the main provisions of the 1994 Agreement, are:

• The PA who will be performing professional duties of a pharmacist in his/her temporary absence shall be employed in the pharmacy concerned on a permanent basis for not less than 15 hours per week;
• The PA shall be entitled to cover short absences, such as lunch hours, two half days or one day off per week, unscheduled short absences and the standard annual leave of the pharmacist;
• The maximum number of days which the PA could cover in the temporary absence of the pharmacist should not exceed 14 calendar days in any single absence.

Current Legislative Framework

The 2007 Act (as amended) and the Regulations made thereunder create a clinical governance structure and framework within which each registered retail pharmacy business (RPB) must comply and operate. It creates distinct pharmacist roles within the RPB practice which may be summarily described as follows:

• The "Superintendent Pharmacist" is the individual registered pharmacist who, having not less than three years whole-time practice experience as a pharmacist in a retail pharmacy business, is in personal control of the pharmacy and as such is responsible for the overall professional and clinical management of the pharmacy. This pharmacist is in personal control of the management and administration of the sale and supply of medicines, and may operate in this capacity for more than one pharmacy practice at a given time. (ref. Sn 27(b), 28(a) and 29(b) of the Pharmacy Act 2007) The Superintendent pharmacist has legislative and professional obligations to ensure that all staff under his /her management have the requisite knowledge , skills, including language skills and fitness to perform the work for which they are, or are to be responsible. (ref. regulation 5(1)(h) of The Regulation of Retail Pharmacy Businesses Regulations 2008)

• The "Supervising Pharmacist", who must also have not less than three years post registration practice experience, is the individual registered pharmacist who is in whole-time charge of the operation of the individual pharmacy business. This pharmacist is responsible for all the on-going operations of the pharmacy, even when absent and has a reporting relationship to the superintendent pharmacist. The pharmacist fulfilling this role may operate in this capacity for one pharmacy only at a given time and is required to have his or her name conspicuously displayed at the pharmacy premises concerned. (ref Sn 27(c), 28(b) and 29(c) of the Pharmacy Act 2007).

• The "registered pharmacist" is that pharmacist who, either personally or under whose personal supervision the sale and supply of medicinal products in the pharmacy is conducted. No post-registration experience is laid down for this pharmacist unless he or she is acting as the Superintendent Pharmacist and/or the Supervising Pharmacist for the particular retail pharmacy business. In all cases, the registered pharmacist(s) operating in a pharmacy that delivers pharmacy care and services are required to comply with all legislative requirements, including the Code of Conduct for pharmacists, any guidance given by the Regulator and appropriate internal policy procedures and protocols. Such pharmacists are also personally accountable for all professional practices and activities overseen or carried out by him or her in the conduct of the business.

Under Section 26 of the Act, it is an offence to carry on a retail pharmacy business other than in accordance with the conditions set down in each of sections 27, 28 or 29 of the Act (depending on the type of pharmacy owner i.e. natural person, limited company, representative). In all instances, irrespective of the pharmacy ownership structure, the sale and supply of medicinal products must be carried out by or under the personal supervision of a registered pharmacist at all times. (ref. Sn 27(d),28 (c)and 29(d)) Section 30 of the Act provides that no offence is committed under Section 26 of the Act where a registered pharmaceutical assistant acts on behalf of a registered pharmacist during the temporary absence of the registered pharmacist.

A Pharmaceutical Assistant is permitted therefore, to carry out the activity of a registered pharmacist in the temporary absence of that pharmacist insofar as the sale and supply of medicinal products in a retail pharmacy business are concerned (vide Sn 27(d), 28 (c) and 29(d) of the Act) but not those functions that would be specifically associated with the roles of Superintendent and/or Supervising Pharmacist. Pharmaceutical assistants are not currently subject to Fitness to Practise provisions outlined in Part 6 of the Act, nor are they required to maintain competence as a criteria for annual continued registration.

Drivers for Change

The Pharmacy Act 2007 (the Act) changed the regulatory framework within which the practice of the profession of pharmacy occurs, in the interest of the health, safety and welfare of patients and the public. The Act introduced Fitness to Practise and mandatory continuing competence requirements for pharmacists, and introduced a new regulatory regime for pharmacy businesses. It introduced wide ranging, new regulatory safeguards applicable to pharmacists and pharmacies who are involved in the delivery of irreparable care and treatment to patients, which were not present under the self-regulation model which was in place prior to the Act's enactment.

The Act, irrespective of a pharmacy's ownership structure, provides 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, with the only exception arising being when a registered Pharmaceutical Assistant (*previously "Assistant to a Pharmaceutical Chemist" under previous legislation*) acts in the *temporary absence* of the pharmacist. When the Act was enacted, a specific authority was given (under s.30) by the Oireachtas to the regulator to define:

1. what constituted the temporary absence of a pharmacist from a pharmacy, and
2. what may be or may not be done by a pharmaceutical assistant when acting on behalf of a registered pharmacist.

The Act formalised the governance framework in place in the context of the operation of a clinical pharmacy practice. Patients thereafter may hold an expectation of certain structures and consistency of service being available in every pharmacy s/he accesses, particularly in the context of the availability of pharmacist availability and attendance. Furthermore it would be ideal that there is clarity available to a patient attending a pharmacy practice as to identity and qualification of the practitioner or pharmacy personnel s/he interacts with.

In October 2013 a Memo was presented to the Council of the PSI, the subject matter of which had previously been considered by the Inspection and Enforcement, and the Registration and Qualification Recognition Committees of the PSI Council. The Memo highlighted that during inspections some Pharmaceutical Assistants had been found to be working outside the terms of the Agreement with the Pharmaceutical Assistants Association, regarding covering temporary absences. This Memo detailed that out of 135 pharmacy inspections carried out in the first months of 2013, Pharmaceutical Assistants were employed in 62 pharmacies. In 35 of these pharmacies Pharmaceutical Assistants were found to be working outside of the terms of the current agreement in place, under the agreed Code of Practice, with issues relating to locum employment or working for periods of time covering "temporary absence" in excess of that specified in the agreement. The table below details the statistics over the period 2012-2016.

	Non-Compliance Statistics				
	2012 N=60	2013 N=387	2014 N=624	2015 N=144	2016 N=149
Number of pharmacies inspected which had a Pharmaceutical Assistant providing professional cover	32%	28%	27%	22%	17%
Pharmaceutical Assistant providing professional cover in the temporary absence of the pharmacist, not in accordance with the terms of the Code of Practice Governing the Temporary Absence Clause of the Pharmacy Act 1980 (issued 1994)	74%	49%	63%	63%	50%

N= Number of inspections carried out in a given year

In circumstances where a health profession should be regulated when unregulated practice can clearly harm or endanger the health, safety, or welfare of the public; where the potential for the harm is easily recognisable and not remote or dependent upon tenuous argument; where the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and the public cannot be effectively protected by other means in a more immediate cost-beneficial manner, the Council in exercising its authority as conferred by the Oireachtas directed that a policy position be developed to enable and facilitate the drafting of rules in line with the requirements of Section 30(2) of the Act.

In seeking to progress the drafting of rules the PSI engaged with interested parties on numerous occasions. In summary:

- October 2013 –Council directed that a policy position be developed to enable and facilitate the drafting of rules in line with the requirements of Section 30(2) of the Act.
- Registration and Qualification Recognition (RQR) Committee was assigned responsibility in the PSI Service Plan 2014 – the expertise of a Pharmaceutical Assistant was sought and one joined the Committee in March 2014.
- PSI met with representatives of the Pharmaceutical Assistants Association on the 23rd May 2014 - a proposed project plan was described at this meeting.
- 3rd July 2014 - a targeted request for submissions to inform policy development was initiated.
- The matter of temporary absence Item was considered by Council in public session on Oct 14, Dec 14 and Mar 15.
- Considered by RQR Committee and Inspection and Enforcement Committee on a number of occasions.
- Considered at a Council policy session Oct 15
- Considered in private session Dec 15 Council meeting and a draft set of Rules was approved for public consultation. These rules focussed on what constituted the temporal limits that a pharmacist could be absent from a pharmacy, with an intent thereafter that the Council could then proceed to examine what tasks and functions should be discharged by a Pharmaceutical Assistant in the absence of the pharmacist.
- The public consultation on a draft set of Rules commenced in Feb 16, and the consultation concluded on 7th March 2016. The Council also considered the matter at a policy session on the 14th April 2016, where

it was briefed on the feedback received and discussed at a macro level the issues arising without making any determination or decision.

- At its meeting on 23 March 2017, the PSI Council reviewed the responses received through the public consultation process on the draft Rules. Following this consideration, the Council made the decision not to recommend the draft Rules to the Minister, under Section 30 of the Pharmacy Act 2007, and instead directed that the matters be re-examined with further consideration to be given to what could be covered within the scope of Rules, as provided for under Section 30 (2) of the Act. The Council acknowledged that the status quo position in relation to the 1994 Code of Practice still pertains.

In these circumstances, and in the context of progressing matters a working group was established which was tasked with assisting in the work and progression of the development of Rules to be constituted under the provisions of Section 30 of the Pharmacy Act 2007. (See Appendix Two)

Working Group – Meeting One

The first meeting of the Working Group convened on the 21st July 2017.

Attendees : John Bryan
Georgina Farren
Damhnait Gaughan
Joanne Kissane
Rita O'Brien

Apologies : Ann Sheehan

Agenda : 1) Terms of Reference
2) Definition and discussion of current status
Current Practice
Legal perspective
Potential Options
3) Preliminary Policy discussions

Discussions :
A presentation was delivered to frame and understand the requirement being asked of the working group. This summarised the legislative provisions in place and contextualised the position and the parameters for discussion.

The proposed terms of reference for the group were circulated and agreed. It was noted that ROB raised the issue of potential inclusion of another registered PA to participate in the working group.

The current framework in place governing the understanding of temporary absence was examined. A discussion/work through of the provisions were undertaken to allow discussion and formulation of proposed recommendations for inclusion in rules. Other topic considerations which arose related to the genesis and terms of the qualification as PA, current operational activities of PA, CPD obligations in the context of the role of PA, Fitness to Practise provisions, public and patient safety and protection, implications on the employability of PA's in the event of restrictive regime, code of practice was not a legally enforceable provision, capability of PA, supervision principles applicable to PA and pharmacist, difference between managing a pharmacy and operating, accountability if pharmacist not there, difference between PA and technician, examination of two facets – time and scope of practice, clinical management role should reside in pharmacist, minimal cross over and holiday cover.

The discussions were premised in the potential viewpoint of a patient attending a pharmacy and the expectations/he may hold in the context of the availability of a pharmacist in the practice at all times,. While the working group made specific recommendations regarding the time limits of temporary, these were specifically contextualised in the framework of how long the regulator would deem it permissible for a pharmacist to be absent from the pharmacy.

The recommendations arrived at are proposed on the basis of a considered majority decision – these were not unanimous or arrived at by consensus and significant disparate views were held by the group membership.

Outcome :

Subsequent to discussions the following criteria were identified as being appropriate recommendations for inclusion in a draft set of rules regarding how long pharmacist could be absent from a pharmacy in circumstances where a PA operated in the temporary absence of that pharmacist – these were not unanimously agreed but were arrived at through a majority decision.

- Requirement that in circumstances where a PA operates in the temporary absence of the pharmacist that the registered Pharmaceutical Assistant and Supervising Pharmacist/Pharmacist must be present on a cross cover basis.
- Retention of the requirement that in circumstances where a PA operates in the temporary absence of a pharmacist s/he should be employed in that pharmacy practice for a minimum of 15 hours per week.
- A pharmacist may only be absent from a pharmacy, in circumstances where a PA operates in the temporary absence of the pharmacist, for a maximum of period of one hour per day.
- A PA may not cover in the temporary absence of a pharmacist for holiday cover

Working Group – Meeting Two

The second meeting of the Working Group convened on the 26th September 2017.

Attendees : John Bryan
Georgina Farren
Damhnait Gaughan
Rita O'Brien
Ann Sheehan

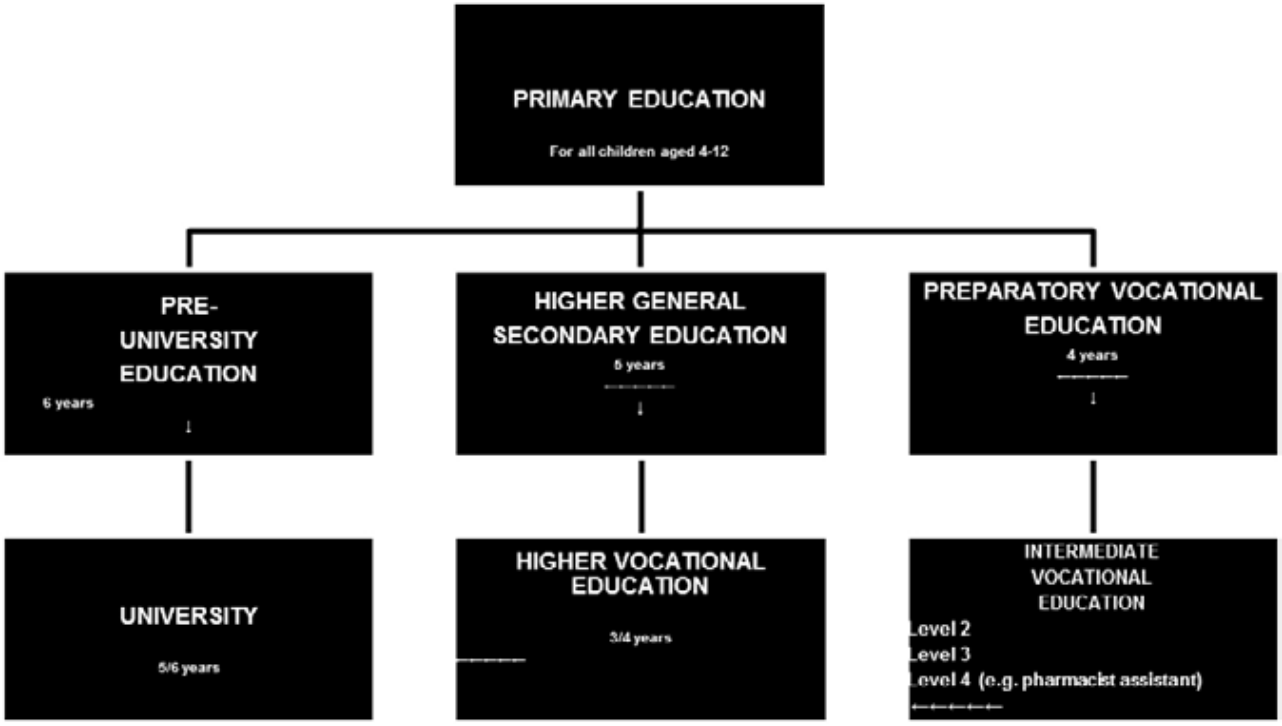
Apologies : Joanne Kissane

Agenda :
1) Consider any other healthcare professionals and models which operate in a similar and/or equivalent framework
2) Review factors and potentially transferable principles and criteria arising in other healthcare and relevant sectors and consider impact in policy and rule development
3) Discussion on a confidential basis report produced by NARIC UK in the context of benchmarking of qualification
4) Consider and discuss in the context of the legal and policy framework in place what the working group considers is appropriate to be done when a pharmacist is temporarily absent from a pharmacy
5) Discuss whether any particular stakeholder views should be sought

Discussions :
A brief review of the presentation given at the first working group meeting was given.

Consideration of potential relevant circumstances pertaining to other healthcare professionals and healthcare models, which operate in a similar and/or equivalent framework were mooted. In this context a number of considerations arose, and were discussed including other associated health professional regulatory mechanisms as applied by CORU in the case of social workers –(potential grandfathering arrangements), and the potential applicability in the Irish system and context of the mechanisms of regulatory governance which are relevant in the case of pharmacy assistants in the Netherlands.

It appears that pharmacists' assistants in the Netherlands have a greater degree of independence from pharmacists than in Ireland, and appear to exercise a significant role in the day-to-day running of the pharmacy. In the Netherlands, you can become a pharmacy assistant in 2 ways. First, through a 3-year theoretical course which includes internships at various pharmacies. These practical trainings make up for about 30% of the course. The second is an apprenticeship model - students aged 18 or over will work in a pharmacy for at least 24 hours a week. They will also attend school 2 evenings a week, in order to become a professional pharmacy assistant. Training for pharmacy assistants comes in the form of a course at Intermediate Vocational Education, level 4 within the Dutch system, as illustrated in the diagram below.



Consideration was not given to mapping or to the equivalency of qualification of the Irish Pharmaceutical Assistant qualification and the Pharmacy Assistant qualification in the Netherlands, nor was the practice environment analysed to the extent that equivalency of differences between the two health care systems were assessed.

Discussions occurred in respect of the potential application of partial access under the terms of the Professional Qualifications Directive. The group briefly discussed the UK Responsible Pharmacists Regulations in the context of the length of time the pharmacist can be absent (maximum of 2 hours within a 24 hour period) and the activities that may be undertaken during the pharmacist's absence.

Discussion ensued relating to the report compiled by NARIC further to the independent evaluation completed by them of the Pharmaceutical Society of Ireland's (PSI) legacy Pharmaceutical Assistant qualification, in the context of the UK education system using the Regulated Qualifications Framework (RQF) in England, Wales and Northern Ireland as the main reference point. This report benchmarked the qualification so as to confirm overall to RQF Level 3 standard, which would be equivalent to level 5 of the NFQI.

Various viewpoints were expressed in the context of this report and points raised included how the qualification could be so benchmarked when a Leaving Certificate was necessary to gain access; were there potential mechanisms to raise the level of the qualification; what was the public perception and expectations in the context of the professional in jurisdiction of a pharmacy practice; non applicability of fitness to practice and CPD. It was noted that temporary absence and the provisions of Fitness to Practice and

Continuing Professional Development are separate matters. Amendment of primary legislation would be necessary to allow for application of these frameworks to Pharmaceutical Assistants.

Discussions also evolved in respect of liability and public expectation. The landscape in respect of public health was referenced in the context of the Pharmacy Act creating an expectation and ethos that it would only be in limited circumstances that a pharmacy would operate without a pharmacist – i.e. that the frame "temporary absence" would be costumed narrowly.

The impact of costuming temporary absence narrowly was discussed. The impact in respect of employability of Pharmaceutical Assistants was raised particularly if there were restrictions in respect of the ability to provide holiday cover, or on the activities that could be conducted in the temporary absence of the pharmacist. It was acknowledged that this may be an issue however the regulatory remit could only focus on the public safety and protection facets of the discussion. The gap between the level of qualification held as a pharmacist and a pharmaceutical assistant as evidenced by the NARIC report was concerning in the context of the current regulatory framework. Not all of the working group members were satisfied with the report.

Outcomes :

- Further review by group membership of the qualification in place in the Netherlands, and the governance framework in place in respect of scope of practice and regulatory responsibility.
- Consideration of the scope of practice of a pharmaceutical assistant to be progressed at next meeting
- Circulation for consideration by group membership of the address given by the Chairperson of the Pharmaceutical Assistants Association to Council on the 23 March 2017
- Review of the legislation in place in the UK in respect of permissible duration of absence of the responsible pharmacist, and the activities that may be undertaken in that absence.

Working Group – Meeting Three

The third meeting of the Working Group convened on the 19th October 2017.

Attendees : John Bryan
Georgina Farren
Damhnait Gaughan
Joanne Kissane
Rita O'Brien
Ann Sheehan

Agenda :
1) Consider any other healthcare professionals and models which operate in a similar and/or equivalent framework
2) Review factors and potentially transferable principles and criteria arising in other healthcare and relevant sectors and consider impact in policy and rule development
3) Discussion on a confidential basis report produced by NARIC UK in the context of benchmarking of qualification
4) Consider and discuss in the context of the legal and policy framework in place what the working group considers is appropriate to be done when a pharmacist is temporarily absent from a pharmacy
5) Discuss whether any particular stakeholder views should be sought

Discussions :

At this meeting the focus moved from what defined the length of absence of a pharmacist to what could be done in the absence of the pharmacist.

A matrix was compiled which could summarily, at a high level capture the activities of a pharmacist in a community practice. The group then proceeded to discuss the activity matrix and suggested whether the activity should fall within the scope of practice of the PA, on the basis of the perceived risk associated with the particular activity.

It was noted that while a Competency Framework existed for pharmacists, a similar framework was not in place for Pharmaceutical Assistants. It is arguable in the context of a circumstance where a Pharmaceutical Assistant operates in the temporary absence of a pharmacist, as to whether it would be expected that the Pharmaceutical Assistant be subject to and required to display all the competencies required of a pharmacist.

In the context of the NARIC report which determines a significant gap between the level of qualification held it may be more appropriate to expect that a Pharmaceutical Assistant demonstrate profile and learning outcomes of a training program which should be regarded primarily as a description of the capabilities that must be achieved to ensure that the Pharmaceutical Assistant is properly prepared for this professional role, in terms of both practice in this role and providing cover in the temporary absence of a pharmacist should this circumstance arise.

Working Group – Meeting Four

The fourth meeting of the Working Group convened on the 15th January 2018.

Attendees : John Bryan
Damhnait Gaughan
Joanne Kissane
Rita O'Brien
Ann Sheehan

Apologies: Georgina Farren

Agenda: Discussion, formulation and potential approval of Working Group Report incorporating a proposed draft set of Rules

Discussions: An initial draft report was issued to the group electronically in advance of the meeting - this was a preliminary working draft to aid discussions at the meeting. The group considered the format and layout and accepted as proposed, with minor modification of headings. It was agreed that the document would be shared through One Drive to allow all participants contribute to the formation of the final document.

Discussion reverted to consideration of some of the previous positions adopted and it was queried as to whether some of the decisions made were taken too hastily, and in advance of certain information being distributed to the group. The equivalence of certain training courses was mooted, particularly in the context of the roles of "pharmacist assistant" in the Netherlands, "pharmaconomist" in Denmark and "prescriptionist" in the Nordic states. It was indicated that in each of these professional classes, while the individual holding the qualification was not a pharmacist that s/he was in a position to dispense prescription controlled medication under particular frameworks, which differed in each state in terms of duration, governance and supervision. It was stated that these particular situations established that there was a precedence whereby differing levels and type of qualification conferred access to a particular professional activity.

The group had been circulated with a set of notes originating from individuals who had undertaken the Pharmaceutical Assistants qualification. The group had previously been circulated with report from NARIC, which was an independent and objective evaluation of the Pharmaceutical Society of Ireland's (PSI) legacy Pharmaceutical Assistant qualification in the context of the UK education system using the Regulated Qualifications Framework (RQF) in England, Wales and Northern Ireland as the main reference point. The group noted the material provided but did not hold itself out to have expertise in the evaluation of this. Discussion also ensued regarding the potential applicability of the ECTS system in the context of the legacy qualification.

The impact of restricting the ability of a pharmaceutical assistant to provide cover in the temporary absence of the pharmacist was raised. The probability of any restrictions to temporary absence cover impacting employment status and potential employability was of concern to some of the group members. The position was also expressed in the context of this discussion that the legislation was in place from a public protection standpoint, and that while changes in law can have consequent and extraneous impacts that a particular framework was envisaged and provided for by the Oireachtas, and PSI would have to deliver on this.

Further discussion evolved regarding the absence of Continuing Professional Development, and whether obligatory Continuing Professional Development would negate the necessity or desire to define the acceptable duration of temporary absence of the pharmacist. Material including copy legal advice provided by one of the group membership, was referenced in the context of applying Fitness to Practice and Continuing Professional Development provisions to pharmaceutical assistants. It was suggested that the optimum way to ensure public protection was to ensure that pharmaceutical assistants would be professionally liable for any act or omission. The rationale for recommending 1 hour was described as a mechanism to reduce risk.

A point was made that the framework within which pharmaceutical assistants had covered in the temporary absence of the pharmacist was in existence for the last 40 years. It was suggested that the activities described as high risk were as risky for pharmacists as pharmaceutical assistants, and that more errors would be made daily statistically by pharmacists. The idea that a pharmaceutical assistant could not dispense a prescription to initiate therapy was disputed. The role of the supervising pharmacist was discussed again in the context of clinical management vs supervisory and operational management responsibilities.

The rights and qualifications of the pharmaceutical assistant were raised. It was noted that Continuing Professional Development and Fitness to Practice considerations were outside the scope of the group and that the task involved addressing an immediate risk scenario, not medium or long term aspects.

Outcomes:

Further consideration by the group of all material provided with a view to feeding into the development and formulation of a report.

Working Group – Meeting Five

The fifth meeting of the Working Group convened on the 27th March 2018.

Attendees : John Bryan
Georgina Farren
Damhnait Gaughan
Joanne Kissane
Rita O'Brien
Ann Sheehan

Agenda: Discussion, formulation and potential approval of Working Group Report incorporating a proposed draft set of Rules.

Discussions: The initial draft report issued to the group electronically using One Drive had been reviewed and commented upon in advance of this meeting. The purpose of the meeting was to review all comments, and the document to further progress the report. All comments made were separately addressed and a group consensus arrived as to what individual action be taken in the context of the report. Other issues arose in respect of content and additions of material and these too were actioned.

Particular discussions evolved on certain of the comments submitted. The particular constitution of the group was discussed in the context of a report being produced based on the opinions of the membership of the group. The consensus of the group was that it was properly constituted based on the individual competencies identified as being useful in addressing the task assigned. It was noted that the remit of the group was to deliver a report and the decisions evolving from this were a matter for the Council and ultimately the Minister.

Discussion occurred around the qualifications and responsibilities of pharmaconomist, pharmaceutical assistants and prescriptionists in their respective states of origin, in the context of the health system that applied in each respective state. It was noted that to directly translate the frameworks was difficult in that each state had differing global health system controls in place e.g. demographics, requirements for patients to register with a particular pharmacy practice.

Discussion ensued regarding the NARIC report. Further potentially relevant material had become available and it was suggested that the study be redone. The majority view on this was that the agency responsible would not have carried out the initial report assessment if it did not perceive that sufficient material was available to it to arrive at a conclusion, and would not have expressed conclusive opinion in the absence of this. Questions were raised as to whether the pharmaceutical assistant qualification should have been compared to the pharmacist qualification in place at that time. It was stated that this was not what the report was based on; the qualification was benchmarked against a qualifications framework and not against a particular qualification from a different profession. The full NARIC report would also be presented to the Council as it had not yet obtained a copy thereof, and no changes could be made to an independent report notwithstanding that particular comments could be made by any individual who wished to within the framework of the temporary absence working group report.

Discussion ensued regarding legal opinion and the applicability of Fitness to practice and Continuing Professional Development, as well as reference to an ESRI report around Pharmaceutical Services in Ireland produced in May 1970.

Outcomes: Further consideration by the group of agreed actions at this meeting. All participants to have completed particular edits and additions by the 14th April. The document would thereafter be closed and circulated in final draft form to the group in advance of submission to the RQR Committee at its meeting scheduled for the 1st May.

Discussion

The output required from the working group is to prepare a report based on the findings of its discussions, incorporating a recommendation for policy options in respect of Section 30, and to propose a draft set of rules for recommendation and consideration by Council. (*These rules are drafted in advance of legal review and are only a suggested mechanism for instituting the policy position arrived at in discussion and a preliminary attempt at instituting this position - they may be reformulated subject to legal review*).

The 2004 White Paper "Regulating Better" delineated principles for regulation in the context of the Irish regulatory landscape, including consideration of the necessity, effectiveness, proportionality, transparency, accountability and consistency of any regulatory action inducted. The previous mechanism of regulating was based on an agreement between the Pharmaceutical Assistants Association and old Pharmaceutical Society of Ireland which was a mechanism of stipulating an agreed position or understanding of what constituted temporary absence. This was not adhered to in all circumstances, and legal certainty along with clear accountability pathways did not prevail. The changed regulatory framework introduced by the Pharmacy Act 2007 clearly outlined a mechanism whereby patients' expectations of appropriate regulatory protections was created. Pharmaceutical assistants fall outside the current regulatory disciplinary mechanism with no disciplinary recourse against the actions taken by any individual pharmaceutical assistant available. Rules are necessary in that they will be binding; they will apply to all pharmaceutical assistants; they will provide certainty to pharmacists, pharmacy owners and to pharmaceutical assistants; and rules will provide a clear basis for prosecuting non-compliance.

The discussions of the working group were comprehensive and addressed throughout certain issues that did not fall within the remit of the work that group had been tasked with addressing. The context of the discussions was countenanced in the premise that the Regulator had to arrive at a position, in the context of the framework provided in the Act, as to what length of time it was permissible for a pharmacy practice to operate in the absence of a pharmacist. The exemption provided in the Act is an exceptional provision, which provides an exception to the standard framework of control and governance provided under the Act and as such the working group costumed the policy position proposed narrowly.

The NARIC report commissioned by PSI was significant as this was the first independent assessment of the qualification. This was conducted by the National Recognition Information Centre for the United Kingdom (NARIC), the national agency responsible for providing information and expert opinion on qualifications and skills worldwide in that jurisdiction. In conducting the study UK NARIC indicated that it had "tailored its established methodology for credential evaluation to review the PA qualification's core design components, including quality assurance measures, and to identify standards (i.e. learning outcomes) to draw comparisons with RQF knowledge and skill expectations for different qualification levels in the UK education system. The RQF (Regulated Qualifications Framework) was selected as the main reference point for comparing the pharmaceutical assistant qualification in the UK education system because it is designed for general and vocational qualifications and is outcomes-based (i.e. describes the knowledge and skills gained on completion of a qualification). In addition to the RQF, to further inform the comparison the study considered similarly-focussed qualifications, where appropriate".

The review by UK NARIC found "Overall, on consideration of the range of knowledge and skills and breadth and depth of outcomes identified in the PA qualification circa 1958-1985, UK NARIC finds the PA qualification comparable to RQF Level 3 standard in the context of the UK education system". This standard equates to a level 5 on the Irish framework or Leaving Certificate standard. A copy of the Executive Summary of the UK NARIC report is attached as Appendix 5. UK NARIC did acknowledge the limitations of reviewing a course that was offered for 20 years and was last offered 30 years ago. The main points from the summary are:

- Overall, on consideration of the range of knowledge and skills and breadth and depth of outcomes identified in the PA qualification circa 1958-1985, UK NARIC finds the PA qualification comparable to RQF Level 3 standard in the context of the UK education system.
- The main scientific knowledge principles covered in the PA qualification can be clearly seen in the curriculum of similarly-focussed RQF Level 3 qualifications today, for example, under chemical and biological principles in pharmacy, microbiology, human physiology, the action and uses of medicines, infections, immunological products and vaccines.
- Pharmacognosy is not specifically referenced in the syllabuses of similarly-focussed RQF Level 3 qualifications in the UK today, however, knowledge of equivalent poison and other relevant legislation as well as supply of dressings and surgical hosiery is required.

The 2007 Act has changed the general statutory context within which the interpretation to be given to the phrase "temporary absence" falls to be considered as the phrase must be costumed narrowly, as it is designed to put in place an exception to the general prohibition on operating a pharmacy without a pharmacist being present. The Working Group understood that the Act clearly empowers the Council to define what is meant by temporary absence and it is a matter for the Council, acting reasonably, to define this. The expectation of a patient that a pharmacist be accessible and operating within a pharmacy is conserved in the legislative framework, and the PSI in the context of its core Corporate Objective to assure trust in pharmacy services is to define for how long it thinks it is acceptable for a registered Retail Pharmacy Business to operate in the absence of a pharmacist.

Temporary absence of a registered pharmacist – Considerations of Section 30 of Pharmacy Act 2007

The majority of the Group acknowledged and accepted the tenet of the Pharmacy Act which required that the sale and supply of medicine be conducted under the personal supervision of a registered pharmacist. The Group were mindful of the change in medicines and complexity of medicine regimes over the past 20 to 30 years, the introduction of the High-Tech Scheme which accounts for 25% of GMS costs a case in point and feel that public safety is assured through the provision of pharmacy services by registered pharmacists. The majority of the Group are of the view that the circumstances under which a registered pharmacist is allowed leave a pharmacy to be operated in their absence by a non-qualified pharmacist should be exceptional and if allowed should be of a very limited duration.

The majority of the Group felt that public safety must be the overriding criteria on which any model under Section 30 of the Act is developed and that is best achieved through the provision of services by a registered pharmacist. However, the Group also acknowledges the exception provided within section 30 of the Act and acknowledges the legacy services of Pharmaceutical Assistants, it also acknowledges the limitation of the qualification of a PA and notes that pharmaceutical assistants are not subject to fitness to practice provisions under the Pharmacy Act 2007 and in these circumstances arrived at the recommendation that a registered

pharmacist may be absent from a pharmacy for one hour per day and a Pharmaceutical Assistant who is familiar with the operation of the pharmacy having worked under the supervision of the pharmacist or supervising pharmacist on a regular basis may act in the temporary absence of the pharmacist for the duration of one hour.

Scope of Practice Pharmaceutical Assistants During Temporary Absence

In determining what may or may not been done by a registered pharmaceutical assistant while acting on behalf of a registered pharmacist the Group were influenced by:

- The NARIC Report and the limitation of the qualification of pharmaceutical assistants highlighted by the report. The qualification achieved by PA's was considerably below the qualification of registered pharmacist at the time that both were awarded. Obviously the qualification for PA's has not been awarded from the 1980's and since then the qualification for registered pharmacist moved to a four year academic degree and one year working within a pharmacy and has moved to a five year integrated programme.
- The fact that PA's have not undertaken CPD and the Pharmacy Act 2007 does not require CPD for PA. This is a moot-point in that the qualification itself is well below the standard required of a pharmacist and CPD could not make up for the deficiency in qualification outlined in the NARIC report.
- Pharmaceutical Assistants are not subject to fitness to practice. This highlights a significant deficiency from the public perception. Patients attending pharmacies assume that they are dealing with a fully qualified pharmacist, they also assume that they have recourse to a statutory complaints process should the need arise. Neither of these assumptions can be met if a PA provides the service.
- It also took into account the changing face of pharmacy practice, the introduction over the years of highly complex medicine regimes.
- The significant increase in the utilisation of high-tech arrangements and the significant risks associated with the dispensing of such medicines. This scheme was introduced in November 1996. In 1998 medicines to totalling €25,047m were dispensed in pharmacies. In 2016 this figure had risen to €611,737m. Medicines dispensed under this scheme are complex and include many items that are high risk.
- When the vaccination scheme was introduced in pharmacy PA's were excluded under relevant provisions as person authorised to administer vaccinations.

In consideration of the above factors the Group undertook a risk assessment of the work that could be undertaken by a pharmaceutical assistant during the temporary absence of a registered pharmacist and assessed the risk to patient safety of utilising persons with limited qualifications to undertake the full range of tasks undertaken by a registered pharmacist. A list of tasks were risk assessed. In summary it essentially recommends that a PA be allowed to repeat therapies that have been initiated and assessed by a registered pharmacist, but the assessment and dispensing of all new therapies would be outside the scope of practice of a pharmaceutical assistant.

In all areas of the health service information to the public is regarded as essential to develop trust and an informed public. To this end the Group also recommends that all persons involved in the provision of pharmacy services to the public be clearly identified and their qualification or registered status also be

clearly identifiable to the public. The Group acknowledges that this recommendation maybe strictly outside the scope of section 30 of the Act and its terms of reference but advocates for the inclusion of such a provision in the interests of providing valuable information to the public.

Recommendations for Rule Development

Policy recommendations to be included in the Rules, subject to drafting advice are as follows;

- A pharmacist may only be absent from a pharmacy for a maximum of period of one hour per day
- Requirement that in circumstances where a PA operates in the temporary absence of the pharmacist that the registered Pharmaceutical Assistant and Supervising Pharmacist/Pharmacist must be present on a cross cover basis.
- Retention of the requirement that in circumstances where a PA operates in the temporary absence of a pharmacist s/he should be employed in that pharmacy practice for a minimum of 15 hours per week.
- A PA may not cover in the temporary absence of a pharmacist for holiday cover
- Identity of the practitioner and qualification held by the practitioner should be known to ensure clarity for a patient attending a pharmacy practice as to whom s/he interacts with.
- General pharmacy operations and activities should be identified and in the context of risk, an assessment be carried out of particular tasks which could be carried out by persons holding specific qualifications.

Proposed draft Rules - Subject to legal counsel review and approval

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Appendix One – Working Group membership

Working group members	
John Bryan	Head of Regulation PSI
Georgina Farren	Professional Advisor NMBI
Damhnait Gaughan	Head of Education and Registration PSI
Joanne Kissane	Superintendent pharmacist of Lloyds Pharmacy. Council member PSI
Rita O'Brien	Chairperson Pharmaceutical Assistants Association
Ann Sheehan	Business Development Specialist. Patient Advocate. Council Member PSI
Supported by:	
Amanda Keane	PSI Administrative Support

Appendix Two – Terms of Reference

Working Group – Temporary Absence Rule Development

Establishment and Purpose

A working group is to be established to assist in the work and progression of the development of Rules to be constituted under the provisions of Section 30[1] of the Pharmacy Act 2007.

Membership of the Sub-Group

The working group will comprise of 5/6 persons combining expertise across the areas of operation of, management of, and supervision of an RPB including where there is practical use of "temporary absence cover" as currently understood and operated; professional registration and continued competence; regulation; inspection of RPB; risk and quality expertise; public and patient interest/advocacy and policy development. The Working Group will provide expertise, advice and input to assist in developing policy options, and drafting rules.

Objectives

The objectives of the Working Group include to:

- Examine current practice, legal perspective and potential options in respect of the provisions of Section 30 and review in the context of the requirements of the Act;
- Review factors and potentially transferable principles and criteria arising in other healthcare and relevant sectors and consider impact in policy and rule development;
- Avail of external expertise as deemed appropriate by the Working Group and RQR;
- Prepare a report based on the findings containing a recommendation for policy options in respect of Section 30;
- Prepare a draft set of rules for recommendation and consideration by Council.

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[1] . **30**.—(1) No offence is committed under *section 26* where a registered pharmaceutical assistant acts on behalf of a registered pharmacist during the temporary absence of the registered pharmacist.

(2) Rules made by the Council with the consent of the Minister may, for the purposes of *subsection (1)*, provide further as to—

(*a*) what may or may not be done by a registered pharmaceutical assistant when acting on behalf of a registered pharmacist,

(*b*) what constitutes the temporary absence of a registered pharmacist..

Over the duration of the project, it may be necessary for the Working Group to undertake some additional tasks or provide some additional expertise on matters related to the scope of the project.

Corporate Governance

The Working Group is obliged to conduct its activities within the Corporate Governance Framework and rules of the PSI.

Meetings

The Steering Group will meet at least three times over the course of the duration of the project, expected to be no more than 12 weeks, with additional meetings scheduled as needed.

Termination of the Working Group

The work of the working Group will conclude upon the delivery of a draft set of proposed rules to the Council.

Appendix Three - Work Plan

DATE	EVENT	OUTPUTS	ACHIEVED
Friday 21st July 2017	First Working Group Meeting	Consider and agree the Remit and Terms of Reference of the Group Consider current temporary absence provisions and identify any strengths and weaknesses of existing model Gap analysis of current framework to propose time definition as to how long a pharmacist can be absent from a pharm	Completed 21/7/17 Completed 21/7/17 Initial ideas captured 21/7/17
Tuesday 26th September 2017	Second Working Group Meeting	Consider any other healthcare professionals and models which operate in a similar and/or equivalent framework Review factors and potentially transferable principles and criteria arising in other healthcare and relevant sectors and consider impact in policy and rule development Consider on a confidential basis report produced by NARIC UK in the context of benchmarking of qualification Consider and discuss in the context of the legal and policy framework in place what the working group considers is appropriate to be done when a pharmacist is temporarily absent from a pharmacy Discuss whether any particular stakeholder views should be sought	Considered and further information to be sought. Re-examine all issues in meeting scheduled for 19 Oct 2017.
Thursday 19th October	Third Working Group Meeting	Consider any other healthcare professionals and models which operate in a similar and/or equivalent framework Review factors and potentially transferable principles and criteria arising in other healthcare and relevant sectors and consider impact in policy and rule development	Considered and further discussion.

		Consider on a confidential basis report produced by NARIC UK in the context of benchmarking of qualification Consider and discuss in the context of the legal and policy framework in place what the working group considers is appropriate to be done when a pharmacist is temporarily absent from a pharmacy Discuss whether any particular stakeholder views should be sought	Examination of what could be done by PA in absence of pharmacist
Monday 15th January	Fourth Working Group Meeting	Discussion, formulation and potential approval of Working Group Report incorporating a proposed draft set of Rules.	Considered – further discussion and input required. Shared folder to work on Document to be established.
Tuesday 27th January 2018	Fifth Working Group Meeting	Finalisation of Report	Document completed

Appendix Four - Code of Practice governing the Temporary Absence Clause of the Pharmacy Act 1890

6.1 Introduction

The agreement reached between the Pharmaceutical Society of Ireland and the Pharmaceutical Assistants' Association which included a code of practice relating to temporary absence has now been in place since December 1994. At a meeting between the aforementioned bodies it was decided that it might be useful to restate the detailed provisions of the code of practice and elaborate on those areas which have given rise to queries in the intervening period.

6.2 Code of Practice Governing Temporary Absence Clause

6.2.1 The name of the pharmaceutical assistant shall appear in the current Register of Assistants to Pharmaceutical Chemists and he shall have paid the appropriate retention fee

If the name of the pharmaceutical assistant does not appear in the Register of Assistants to Pharmaceutical Chemists (as reproduced in the current calendar), the pharmaceutical assistant should contact the Society to obtain information on how to seek restoration to the register.

6.2.2 The assistant who has not been employed in pharmacy practice during the preceding five years shall undergo a defined period of retraining as required and shall be restored to the register

This provision is not currently being implemented in its entirety. The requirement to undergo a defined period of retraining will not come into force until the Pharmacy Act is passed. Pharmacists who have not been employed in pharmacy practice for a similar time period will also have to undergo such a period of retraining under the terms of the Act. In the interim, such assistants need only apply for restoration to the register.

6.2.3 The assistant who will be performing professional duties of the pharmacist in his temporary absence shall be employed in the pharmacy concerned on a permanent basis for not less than 15 hours per week

An analysis of the annual statements of return (SOR) received from community pharmacies for the year 1995 indicate that a number of pharmacists who employ an assistant(s) for the required number of hours do not appear to employ them to work in their temporary absence or alternatively they omitted to fill out that particular section of the SOR form. Should such pharmacists wish to amend their statements in light of the foregoing we have provided a coupon below which should be sent to the Society giving the amended details.

6.2.4 The assistant shall be entitled to cover short absences, such as lunch hours, two half days or one day off per week and unscheduled short absences

The Pharmaceutical Society of Ireland has been legally advised that the term 'unscheduled short absences' would not be acceptable to the parliamentary draftsmen drawing up the new pharmacy Bill and therefore this will require further discussion. If a pharmacist employs more than one assistant for the requisite number of hours, i.e. 15 hours, he is still only entitled to one day off per week which can be covered by either of his assistants.

6.2.5 In the event of the temporary absence caused by illness of the pharmacist

6.2.5.1 The Society shall be notified as soon as possible, but not later than one calendar week from the date of first absence.

6.2.5.2 If the pharmacist has been absent for a second calendar week the Registrar shall be so informed and the direction of the Registrar in relation to the continuation of cover shall be acted upon by the pharmaceutical assistant who has been covering in the event of such an illness. The operation of this clause in the agreement has proceeded very smoothly since its implementation and no major queries have arisen in respect of same.

6.2.6 In the event of the temporary absence caused by the pharmacist's holiday entitlements

6.2.6.1 The pharmaceutical assistant shall be entitled to cover the period of annual leave as recommended for the employee pharmacist by the Irish Pharmaceutical Union (currently two working weeks per annum).

6.2.6.2 The maximum number of days which the pharmaceutical assistant can cover shall not exceed 14 calendar days in any single absence. Again this particular provision has not caused any problems to date. This provision is however very specific in relation to the entitlements of the pharmacist who is using an assistant to cover such an absence and problems are not anticipated in this regard.

6.2.7 The pharmacist retains full personal responsibility for the supervision and management of the pharmacy.

This provision in the code is extremely specific and no pharmacist can abdicate his responsibility for the supervision or management of the pharmacy under any circumstances.

6.3 General Comments

Where a pharmacist employs more than one pharmaceutical assistant and each of the assistants work the minimum number of hours required in the pharmacy, i.e. 15 hours, the pharmacist can nominate each of the assistants as persons who are entitled to cover in his temporary absence. It was never the intention of the agreement to ask a pharmacist to select one assistant over another or to dismiss an assistant on such a basis. However, no matter how many assistants are employed in a particular pharmacy the pharmacist is only entitled to one day off per week (or two half days per week) with an assistant covering that temporary absence period. The entitlement whereby the assistant can cover short absences still remains.

The SOR forms submitted to the Society have shown that in several instances an assistant is working in more than one outlet and covering the temporary absence of the pharmacist in each outlet. This situation is acceptable provided that the assistant works the required minimum number of hours in each of the pharmacies involved (i.e. 15 hours per pharmacy). If the circumstances prevailing at a particular pharmacy do not appear to be covered by the exact terms of the code of practice detailed above we recommend that the pharmacist concerned should contact the Society and outline the details of the individual case. This will then be examined in detail by both parties to the agreement who shall endeavour to offer some practical guidelines on the matter.

Appendix Five - Executive Summary NARIC report

Benchmarking the Pharmaceutical Society of Ireland's legacy Pharmaceutical Assistant qualification
UK NARIC Benchmarking Report
Submitted to the Pharmaceutical Society of Ireland by UK NARIC
The National Recognition Information Centre for the United Kingdom
The national agency responsible for providing information and expert opinion on qualifications and skills worldwide

June 2017

Commercial in confidence

Executive Summary

In June 2017 UK NARIC completed an independent and objective evaluation of the Pharmaceutical Society of Ireland's (PSI) legacy Pharmaceutical Assistant qualification in the context of the UK education system using the Regulated Qualifications Framework (RQF) in England, Wales and Northern Ireland as the main reference point.

The PSI's Pharmaceutical Assistant (PA) qualification was offered in Ireland between 1958 and 1979, and last awarded in 1985. It consisted of a three-year apprenticeship in an approved community pharmacy followed by an academic course of less than one year's duration at the College of Pharmacy in Dublin and examinations in some subjects. Individuals who successfully passed the examinations entered the PSI's Register of Pharmaceutical Assistants.

In conducting the study UK NARIC tailored its established methodology for credential evaluation to review the PA qualification's core design components 1 , including quality assurance measures, and to identify standards (i.e. learning outcomes) to draw comparisons with RQF knowledge and skill expectations for different qualification levels in the UK education system. The RQF was selected as the main reference point for comparing the PA qualification in the UK education system because it is designed for general and vocational qualifications and is outcomes-based (i.e. describes the knowledge and skills gained on completion of a qualification). In addition to the RQF, to further inform the comparison the study considered similarly-focussed qualifications, where appropriate.

At the outset UK NARIC acknowledges the limitations of reviewing a legacy award offered for over 20 years and last awarded more than 30 years ago, particularly in relation to the type of information (e.g. learning outcomes) and range of documentation available (including undocumented and unsourced PSI notes). Furthermore, there will have undoubtedly been developments in pharmaceutical practice since the time the

PA qualification was developed, delivered and awarded. It is also important to highlight that the study does not provide a value judgement on the job role of Pharmaceutical Assistants in 2017. The comparative analysis outcome of the study is based solely on educational standards identified in the PA apprenticeship, academic course and examination, and whether these were supported by sufficient underlying quality assurance measures.

Overall, on consideration of the range of knowledge and skills and breadth and depth of outcomes identified in the PA qualification circa 1958-1985, UK NARIC finds the PA qualification comparable to RQF Level 3 standard in the context of the UK education system.

The main scientific knowledge principles covered in the PA qualification can be clearly seen in the curriculum of similarly-focussed RQF Level 3 qualifications today, for example, under chemical and biological principles in pharmacy, microbiology, human physiology, the action and uses of medicines, infections, immunological products and vaccines.

1 UK NARIC's established methodology for credential evaluation is based on the principles of the Lisbon Recognition Convention. The core qualification design components considered are: entry requirements; duration; structure and content; learning outcomes; methods of learning; assessment; and associated outcomes.

Pharmacognosy is not specifically referenced in the syllabuses of similarly-focussed RQF Level 3 qualifications in the UK today, however, knowledge of equivalent poison and other relevant legislation as well as supply of dressings and surgical hosiery is required.

Many of the practical skills in the PA qualification are also developed in similarly-focussed RQF Level 3 qualifications in the UK, such as using weights and measures to prepare medicines, keeping records, checking prescription validity and dosages. Furthermore, analysis of the Pharmaceutical Assistant's Examinations from 1983 and 1984 confirm testing of candidates' ability to identify, select and use appropriate cognitive and practical skills, methods and procedures to address well-defined but potentially complex and non-routine problems at RQF Level 3, such as conditions surrounding the sale and supply of medicinal products.

UK NARIC's independent review and evaluation of the legacy PA qualification in the context of the UK education system found strong similarities between all three components of the PA qualification (i.e. apprenticeship, academic course and examinations) analysed within the scope of this study, to RQF Level 3 standard overall. Having reviewed the Articles of Pupillage and identifying other quality assurance measures in place controlling eligibility for the PA qualification and delivery of the qualification at the time, UK NARIC

is satisfied there were sufficiently robust procedures in place to confirm overall comparability of the PA legacy qualification to RQF Level 3 standard.

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Appendix Six – Course Curriculum Content for the Qualification of Assistant to a Pharmaceutical Chemist

PHARMACEUTICAL SOCIETY OF IRELAND

Course for the Qualification of Assistant to a Pharmaceutical Chemist

Pharmaceutics - Theoretical

Weights and measures used in pharmacy; pharmaceutical mathematics. The principles and methods of compounding and dispensing medicines. Incompatibilities in prescriptions. Preparation of Purified Water; Ion Exchange; Distillation & reverse osmosis methods. Granulation and Tabletting; use of adjuncts in tablet manufacture; methods of standardiza of tablets. Method of Sterilisation: Moist Heat, Dry Heat, Filtration. Parenteral Preparations - their formulation and presentation with special reference to the official Monographs of Injections. Production of preparations for Ophthalmic use. Immunological Preparations, Insulins, Blood products. Chemical and physical methods for the preservation of pharmaceutical products, Prolonged action preparations. Containers for pharmaceutical preparations. Medical gases, Disinfectants, Antiseptics and Bactericides.

Practical (approx. 20 sessions)

The dispensing of prescriptions, the detection of unusual dosage. The preparation of a number of B.P. products, including Solutions, Ointments, Creams etc. Simple exercises in sterilisation by heat methods.

PHARMACOGNOSY - Theoretical

Introduction, history and scope of pharmacognosy. Natural products of pharmaceutical importance; a review of the more important plant drugs, their constituents and uses; e.g. Belladonna, Digitalis and Opium. Surgical Dressings, Ligatures and Sutures. Poisonous plants and Fungi. Pesticides and pollution. Oils, e.g. Volatile oils, fats and waxes. Introduction to Bacteria, Viruses and Fungi. A review of some halluncinogenic natural p:roducts and tl1e problem of drug abuse.

PHYSIOLOGY- a brief outline of the anantomy , biochemistry, physiology and pathology of the systems of the human body preliminary to the study of pharmacology.

PHARMACOLOGY - A study of the drugs which influence the body systems with particular emphasis on action, uses, toxicities und possible interaction of drugs. In addition chemotherapy of infections and malignant disease is included.

FORENSIC PHARMACY

The Arsenic Act, 1851, The Sale of Poisons (Ireland) Act, 1870; The Poisons and Pharmacy Act, 1908; The Dangerous Drugs Act, 1934; The Medical Preparations (Advertisenemt and Sale) Regulations, 1958; The Medical Preparations (Control of Sale) Regulations, 1966; Poisons Act, ·1961 (Paraquat) Regulations, 1968; The M1edical Preparation (Control of Amphetamines) (Amendment) Regulations, 1970; The Health (Possession of Controlled Substances) Regulations, 1970 and regula.tions controlling the purchase and sale of spirits.

including methylated spirits and medicated wines, Medical Preparations (Control of Sale) (Amendment) Regulations, 1971; Dangerous Drugs (Amendment) Regulations, 1971.

FORENSIC PHARMACY - Acts and Requla tions

The Arsenic Act 1851 ; T'he Sale of Poisons (Ireland) Act, 1870; •fThe Poisons and Pharmacy Act 1908; ;The Dangerous Drugs A.ct 1934; The Medical Preparations (Advertisement and Sale; Regulations 1958 (S.I. No. 135 of 1958); 'The Medical Preparations (Control of Sale) Regulations 1966 (3.I. No. 261 of 1966); The Poisons Act 1961 (Paraquat) Regulations 1975 (S.I. No.146of 1975); The Medical ?reparations (Control of Amphetamine) Regulations 1969(S.I. No. 244 of 1969); The Medic1tl Preparations (Control of Amphetamine (Amendment) Regulations 1970 (S.I.No. 137 of· 1970); The Health (Possession of Controlled Substances) Regulations 1970 (S. I. No. 99) of 1970); Spirits Regulations; Medical Preparations (Control of Sale) (Amendment) Regulations 1971 (S.I. No. 272 of 1971) ; Dangerous Drugs (Amendment) Regulations 1971 (s. I. No. 273 of 1971); Animal Remedies (Control of Chloramphenicol) Regulations 19-:-4 (S.I. Ho. 10 of 1974); The Health (Possession of Controlled Substances) Amendment 1974 (s. I. No. 55); Medical Preparations (Control of Sale) (Amendment) Regulations 1976 (S.I. No. 82 of 1976); ·Animal Remedies Act, 1956 (S.I. 41 of · 1956) .

TEXT BOOKS

The following are currently being used at the College:

PHARMACEUTICS:

(i) The current edition of the .British Pharmacopoeia,

(ii) Cooper and Gunns' Dispensing for Pharmaceutical Students (current edition)

Students are recommended to be familiar with the following reference books:

British Pharmaceutical Codex, (current edition)

The Extra Pharmacopoeia (Martindale) (current

British National Formulary (current edition).

PHYSIOLOGY & PHARMACOLOGY:

Illustrated Physiology (McNaught & Callendar).

Pharmacology for student and pupil nurses and student pharmacy technicians (Bernard R. J¢Ref. Book :Medicines - A guide for Everybody (Peter Parish).'

Appendix Seven - Risk Assessment Matrix of General Pharmacy Operations

	Can a PA carry out this task	Risk Impact Assessment of task	Qualification held by task requirement	Patient expectation
GENERAL PHARMACY WORK	FACTORS FOR CONSIDERATION The group considered general pharmacy operations and activities in the context of risk assessment based on the task involved. A number of common themes were noted and discussed: • Accountability - Pharmacist retains accountability for all actions within the practice, and the question as to which designated pharmacist the PA is operating in the absence of was raised – this was not settled. • CPD - No compulsory requirement but obligation on SIP and Owner to ensure this is carried out in the event a PA operates in the temporary absence – see SI 488. There is also a legal obligation on a pharmacist to be competent to fulfil the role s/he is engaged in • Competency Framework - Reg. 5 – SI 488 Discussion arose regarding whether a recommendation of the development of a standalone Core Competency Framework for PA's should occur – or should the CCF for pharmacist apply in temporary absence cover			
Personal skills Counter care – advice on medication, medical aids or disease Domperidone and Dovonex must have pharmacist intervention	Yes – subject to caveated activities below	Low	Pharmacist or Pharmaceutical Assistant	All grades of persons in a pharmacy should be identified in the context of identity and qualification
Personal skills Counter other – helping patients otherwise	Yes	Low	Pharmacist or Pharmaceutical Assistant	All grades of persons in a pharmacy should be identified

				in the context of identity and qualification
Personal skills Consultations in consultation room	Yes – excepting initiation of therapy as per below	Low	Dependent on nature of counselling required as linked to the risk impact of the task	
Supply of Medicines Supply and Administration of Emergency Medicines and Vaccinations • Adrenaline injection • Salbutamol inhaler • Glyceryl trinitrate aerosol (sublingual spray) • Glucagon injection • Naloxone injection • Seasonal Influenza vaccine • Pneumococcal Polysaccharide vaccine • Herpes Zoster (Shingles) vaccine	No –only GP/Pharmacist/nurse by law	High	Pharmacist only - pharmacists must complete approved training and obtain relevant certification	
Personal skills Telephone – all telephone work	Yes excepting therapy initiation	High Riskiest form of communication	Dependent on nature of counselling required as	

			linked to the risk impact of the task	
Safe and rational Use of Medicines Emergency supplies at the request of the prescriber	No: when initiating new therapy	High	Pharmacist only	
Safe and rational Use of Medicines Emergency supplies at the request of the patient	No: requires significant decision making and potential consequences for patients are high	High	Pharmacist only	
Supply of medicines online The supply of a non-prescription medicinal product to the public by means of information society services	No – legal requirement that this service is carried out by a pharmacist – SI 87 of 2015	High	Pharmacist only	
Supply of medicines - Pharmaceutical calculations	No	High	All pharmaceutical calculations must be overseen and checked for accuracy by the pharmacist on duty	
Supply of medicines Supply of EHC	No	Med –High Med - High	EHC consultations often complex and should be carried by pharmacists only. Significant clinical decisions often required.	

Accuracy check of MDS	No, where there are more than 5 medicines in the MDS device		Interactions of the medicines removed from their primary packaging and also increased complexity associated with the accuracy checking process.	
Supply of medicines Ex temporare preparations - preparing or making medicines	No	High Not routinely done – needs supervision	Pharmacist only sign-off	
Supply of medicines Dispensing of High Tech Meds Supply of Cytotoxic medicines such as Methotrexate Supply of narrow therapeutic index medications such as Warfarin, Digoxin, Theophylline	No No on initiation or repeat No on initiation or repeat	High High High	Pharmacist only Pharmacist only Pharmacist only	Subject to ongoing clinical management of Pharmacist. Medicines not as well experienced – risk associated with product High risk medicinal products High risk medicinal products
Supply of medicines Dispensing of Controlled Drugs	Yes to Repeat but not initiation assuming no other medicines therapy change	High Risk based on product	Dependent on initiation or continuation	
Safe and rational use of medicines	Initiation of medicines should be carried out under the supervision of a pharmacist	High	Pharmacist only	

Dispensing to initiate a medicines therapy patient has never previously had				
Supply of medicines Dispensing of a medicines therapy patient has previously had	Yes to repeat prescriptions	Low/med.	Pharmacist or Pharmaceutical Assistant	
Supply of medicines Dispensing of Exempt Medicinal Products (EMP) or Unlicensed Medicines	Yes to Repeat but not initiation assuming no other medicines therapy change	High	Dependent on initiation or continuation	
Supply of medicines Paediatric Dispensing	Not on initiation – repeats are acceptable with no changes in therapy	High	Dependent on initiation or continuation	
Supply of medicines Polypharmacy dispensing – patient is using more than 5 medicines	Not on initiation of any new med. – repeats are acceptable with no changes in therapy	High	Dependent on initiation or continuation	
Safe and rational use of medicines Hand out of prescription products previously prepared by pharmacist	Not on initiation – repeats are acceptable with no changes in therapy assuming counselling is done	Low/med. dependent on appropriate communication checks between individuals	Dependent on initiation or continuation	
Safe and rational use of medicines Residential Home care	No	Risk – High polypharmacy, CD's, high techs – complicated regimes with vulnerable patient	Pharmacist only sign-off	
Supply of medicines	Yes	Low	Pharmacist or Pharmaceutical Assistant	

Assembly work - preparatory work in the gathering of a prescription to be dispensed				
Supply of medicines Logistical control work – ordering and handling medical goods Recall or withdrawal of medicinal products either at a pharmacy or patient level	Yes No	Low Med-High	Pharmacist or Pharmaceutical Assistant Pharmacist only	
Administrative work - stock control, claims, expiry dates control and quality system	Yes	Low /med	Pharmacist or Pharmaceutical Assistant	