

**Shadow Report on the PSI Working Group on  
Temporary Absence Report (April 2018)**

**Pharmaceutical Assistants Association**

**June 2018**

## Executive Summary

In summer 2017, a working group was established to assist the PSI Registration and Qualification Recognition (RQR) Committee in the work and progression of rules to be constituted under the provisions of Section 30 of the Pharmacy Act 2007 in relation to temporary absence. The completed report was submitted to the PSI Council on the 17 May 2018. The Council agreed to proceed with developing draft rules under section 30 of the Act, based on this proposed policy. The rules will be considered at the 21 June 2018 Council meeting and a public consultation will take place on these rules over the summer.

This shadow report has been drafted by the Pharmaceutical Assistants Association (PAA) to address aspects of the Working Group on Temporary Absence Report (April 2018) that it is considered are misleading and unfair to the established profession of pharmaceutical assistant, as more fully outlined in the sections A, B and C.

Section A highlights inadequacies identified in the deliberation process including the absence of a robust systematic approach in determining rules for temporary absence. A critical analysis of the deliberation process indicates that a cursory approach was taken in making decisions on complex issues such as what constitutes 'temporary absence'. For example the decision to define the temporary absence of the pharmacist to one hour per day was taken in the first two hours of deliberation based on opinion and perceived and contrived notions of risk not fact or evidence.

Section B points to the failure of the PSI working group to consider its obligations under the Public Sector Equality and Human Rights Duty to ensure the rules are necessary and proportionate. The deliberation process did not review the impact of any rule changes on the rights of pharmaceutical assistants including property rights/right to earn a livelihood. Nor was consideration given to the requirement to compensate pharmaceutical assistants which would flow from a legislative measure which rendered their professional qualifications meaningless or how this would be achieved. The recommendations were developed without reference to wider policy or legislation.

Section C illustrates how the Working Group Report bases its recommendations on a value judgement on the job role of pharmaceutical assistants building a case for restricting this role on inferences and in some instances providing misinformation, such as *"the fact that Pharmaceutical assistants have not undertaken CPD"*.

The shadow report concludes by making recommendations that can provide quality assurance around the competency of pharmaceutical assistants to act in the temporary absence of the pharmacist.

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## Introduction

This shadow report seeks to highlight aspects of the Working Group on Temporary Absence Report (April 2018) which are considered misleading and serve to portray pharmaceutical assistants as a public safety risk making it unfair to the established profession of pharmaceutical assistant (the affected party) in a myriad of ways, as outlined in the sections below.

## Background

Pharmaceutical assistants are persons who have passed the examination prescribed for that purpose by the Council of the Pharmaceutical Society of Ireland. Pharmaceutical assistants are competent pursuant to section 19 of the Pharmacy (Ireland) 1875 (Amendment) Act, 1890 (as amended by section 7(5) of the Pharmacy Act, 1951 and repealed by the Pharmacy Act, 2007) to transact the business of a pharmacist in his “temporary absence” but not “to keep open a shop on their own account”.

Once the qualification was obtained, the qualified pharmaceutical assistant had a statutory entitlement under section 19 of the 1875 Act to transact the business of a registered pharmacist in their absence. Although, the provision enabling the qualification has now been repealed, the right of existing pharmaceutical assistants to continue to practice their profession subsists and is acknowledged by different provisions of the Pharmacy Act, 2007 (not least section 30(1) and section 13 which provide for the maintenance of a Register of Pharmaceutical Assistants).

In 2016, the PSI Council developed a set of draft rules under section 30 of the Pharmacy Act 2007 in relation to temporary absence. A public consultation process took place in relation to these rules. Having considered the matter at its meeting in March 2017, the Council decided to reject the proposal presented, and requested further examination of the issue of temporary absence. A working group was established in the summer of 2017 to assist in the work and progression of rules to be constituted under the provisions of Section 30 of the Pharmacy Act 2007<sup>1</sup>. As outlined in the Terms of Reference for the working group, it was to provide expertise, advice and input to

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<sup>1</sup> Pharmacy Act 2007, **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.

assist in developing policy options and drafting rules<sup>2</sup>. The working group was a sub group of the PSI Registration and Qualification Recognition (RQR) Committee and was to report to them. The working group had six members, four of whom represented the interests of the PSI (see Appendix One for membership of working group). Each member of the working group had to sign a confidentiality agreement.

The objectives of the working group included:

1. Examine current practice, legal perspective and potential options in respect of the provision of Section 30 and review in the context of the requirements of the Act
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. Avail of external expertise as deemed appropriate by the Working Group and RQR
4. Prepare a report based on findings containing recommendation for policy options in respect of Section 30
5. Prepare a draft set of rules for recommendation and consideration by Council<sup>3</sup>

The completed report was submitted to the PSI Council on the 17 May 2018. The Council considered the matter and accepted the Working Group report and its recommendations. It was agreed to proceed with developing draft rules under section 30 of the Act, based on this proposed policy. The rules will be considered at the 21 June 2018 Council meeting and a public consultation will take place on these rules over the summer.

The Working Group Report has been published on the PSI website and provides the rationale for the draft rules proposed. The Report will inform the public consultation. As set out the Open Government Partnership for public bodies engaging with the public when developing policy, services and legislation, a key principle in the consultation

*“must be genuine, meaningful, balanced and with the ultimate objective of leading to better outcomes and greater understanding by all involved of the benefits and consequences of proceeding with a particular policy or legislation proposals”<sup>4</sup>.*

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<sup>2</sup> Page 31 Appendix Two – Terms of Reference Working Group on Temporary Absence Report (April 2018)

<sup>3</sup> Page 31 Working Group on Temporary Absence Report (April 2018)

<sup>4</sup> <https://www.per.gov.ie/wp-content/uploads/Consultation-Principles-Guidance.pdf>

It is considered that a consultation process based on the report of the working group will not be balanced and meaningful. The draft rules subject to the consultation are the product of a partisan process supported by a report that is misleading in its portrayal of the profession of pharmaceutical assistants. This shadow report attempts to redress this extraordinary lack of balance in the report which now appears on the PSI website.

### **Section A: The deliberation process did not adopt a robust systematic approach**

For any decision and any course of action, a wide breadth of evidence should inform the selection of possible strategies to achieve goals. Different kinds of knowledge including scientific, personal experiences and systematic findings from professional inquiries should inform rulemaking. However it is evident from the Working Group Report that the deliberation process for developing temporary absence rules was undertaken in a superficial way.

Considering how the qualification and job role of pharmaceutical assistants is complex and difficult to grasp, coming from legislation commenced in 1890 and being a legacy qualification with the last award being made 30 years ago, the process for developing the recommendations and draft rules took just 10 hours of deliberation in total (5 x two hour meetings). The decision to define 'temporary absence' to one hour per day was made in the first two hours of the deliberation process. It is difficult to see how the depth of knowledge about the job role, experiences and competencies of pharmaceutical assistants warranted for such complex decision-making could be determined within the first hour of deliberation, particularly where the working group members were, in the main, not practicing pharmacists or pharmaceutical assistants. One can only deduce that opinions, notions of perceived and contrived risk and not evidence constructed and guided the assessment of risk to public safety:

- An in-depth analysis of the role, practice and competency of pharmaceutical assistants, all of whom having been practicing for at least 35 years, having passed an examination set by the PSI under Section 19 of the Pharmacy Act (Ireland) Amendment Act 1890 which deemed that they are "*competent to transact the business of a licentiate of the Pharmaceutical Society of Ireland in his temporary absence*" was not undertaken.
- The perspective of key stakeholders including pharmaceutical assistants and independent community pharmacists were not sought. Pharmaceutical assistants did not have an opportunity to share their experiences, their competencies, nor was their engagement with independent community pharmacists who employ and work directly with pharmaceutical

assistants, in some cases over 30 years. These are Superintendent pharmacists who have a legislative and professional obligation to ensure all staff under their management have the requisite knowledge, skills, including language skills and fitness to perform their work, and would therefore be key to inform process on competencies of pharmaceutical assistants.

- An analysis of the Learning from Complaints reports including dispensing errors was not undertaken, nor was there any evidence produced of statistics in relation to dispensing errors made by pharmaceutical assistants.
- There was no in-depth examination carried out of *“potential relevant circumstances pertaining to other healthcare professionals and healthcare models, which operate in a similar and/or equivalent framework”* (Objective 2 of Terms of Reference).

As stated in the Working Group Report, *“consideration was not given to mapping or to equivalency of qualification of the Irish Pharmaceutical Assistant qualification and the Pharmacy Assistant qualification in the Netherlands”*<sup>5</sup>, nor was consideration given to similar qualifications in Denmark and the Nordic countries. This is in spite of the Report noting, from Meeting Two, that *“pharmacy 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”*. These similar qualifications from three other European countries offered *“relevant circumstances”* to provide evidence to weigh up practice and risk in relation to safeguarding public health and safety, but were not followed up. The reasons cited for not examining this potential evidence were the difficulty in directly translating frameworks for qualification as the countries involved *“had differing global health system controls in place e.g. demographic, requirements for patients to register with a particular pharmacy practice”*<sup>6</sup>

- Despite the PSI being set up to protect the safety of the public, consideration of rules under Section 30 (2) to require pharmaceutical assistants to accede to the PSI Core Competency Framework, undertake mandatory Continuous Professional Development, be subject to practice review or amend the Pharmacy act 2007 to include pharmaceutical assistants under Fitness to Practice was excluded for consideration by the Working Group, as outlined in the Report *“temporary absence and the provision of Fitness to Practice and CPD are separate matters”*<sup>7</sup>

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<sup>5</sup> page 13 Working Group on Temporary Absence Report (April 2018)

<sup>6</sup> page 19 Working Group on Temporary Absence Report (April 2018)

<sup>7</sup> Page 15 Working Group on Temporary Absence Report (April 2018)

It is evident from the above points that the processes used to analysis “temporary absence” in the context of the need to safeguard public health and safety was undertaken from a “perceived risk” perspective. The community pharmacy activity matrix, developed by the Working Group actually states this when it outlines how its rationale is based on “*perceived risk associated with the particular activity*”<sup>8</sup>. This ‘perceived risk’ is the basis for recommendations that will forbid pharmaceutical assistants dispensing an antibiotic for a child when working in temporary absence.

## **Section B: Obligations under the Public Sector Equality and Human Rights Duty ignored**

All public bodies in Ireland have responsibility to promote equality, prevent discrimination and protect the human rights of their employees, customers, service users and everyone affected by their policies and plans. This is a legal obligation, called the Public Sector Equality and Human Rights Duty, and it originated in Section 42 of the Irish Human Rights and Equality Act 2014. It is evident from the Working Group Report that no consideration was given to the impact of any proposed rules on the rights of pharmaceutical assistants in circumstances where they now number 336 and, are nearly all women over the age of 55 years:

- There was no engagement with pharmaceutical assistants or community pharmacist to ascertain their practice, competencies, experiences and get their input into developing these recommendations (a member of the PAA was included in the Working Group but was precluded from engaging with the wider members due to the confidentiality clause imposed by PSI)
- Principle of proportionality and non-discrimination was ignored. An impact analysis of the draft rules on the property rights/right to earn a livelihood of pharmaceutical assistants was not alone not undertaken, but even considered so there is no way of the PSI Working Group knowing if the proposed rules are proportionate and necessary. The Report states in relation to the impact of restricting the ability of a pharmaceutical assistant to provide cover in the temporary absence of the pharmacist that “ *the legislation was in place from a public protection standpoint and that while changes in law can have consequences and extraneous impacts that a particular framework was envisaged and provided by the Oireachtas, and the PSI would have to deliver on this*”<sup>9</sup>
- No consideration was given to rules for the mandatory inclusion of pharmaceutical assistants in the PSI Core Competency Framework which encompasses Continuous Professional Development and Practice Review process or Fitness to Practice as mechanisms to safeguard

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<sup>8</sup> page 16 Working Group on Temporary Absence Report (April 2018)

<sup>9</sup> Page 17 Working Group on Temporary Absence Report (April 2018)

public health and safety and protect the public interest. The Report noted that *“Continuing Professional Development and Fitness to Practice consideration were outside the scope of the group and that the task involved addressing an immediate risk scenario, not medium or long term aspects”*<sup>10</sup>

It is evident from points highlighted in Section B, that there has been a patent failure by the PSI Working Group to address the constitutional and fundamental rights of pharmaceutical assistants (not least the right to protection against discrimination on age and/or gender grounds) and the right to earn a livelihood and its associated personal and property rights (protected under Articles 40.3 and 43 of the Constitution and Article 1, Protocol 1, Articles 8 and Articles 14 of the European Convention on Human Rights binding on the PSI under the provisions of the European Convention on Human Rights Act, 2003) in developing and drafting the recommendations and rules for ‘temporary absence’ policy and legislation.

There is no doubt, even with a cursory examination of the recommendations that pharmaceutical assistants’ right to earn a livelihood will be impacted (see Appendix Two for a survey on work practices of pharmaceutical assistants carried out in 2014) and, even presuming that the changes were demonstrated to be necessary following a proper assessment, no consideration was given to the requirement to compensate pharmaceutical assistants which would flow from a legislative measure which rendered their professional qualifications meaningless or how this would be achieved.

### **Section C: Lack of Balance and Misinformation in the Evidence base for the Recommendations**

The Report relies solely on NARIC Report ‘Benchmarking the Pharmaceutical Society of Ireland’s legacy Pharmaceutical Assistant qualification’, commissioned by the PSI, in determining risks around temporary absence for its recommendations and rules governing temporary absence. NARIC used the Regulated Qualifications Framework (RQF) in the context of the current UK education system as the benchmark. Despite the authors of the NARIC Report acknowledging from the outset *“the limitations of reviewing a legacy award offered over 20 years and last awarded more than 30 years ago, particularly in relation to the types of information (e.g. learning outcomes) and range of documentation available (including undocumented and unsourced PSI*

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<sup>10</sup> Page 18 Working Group on Temporary Absence Report (April 2018)

notes)... *The study does not provide a value judgement on the job role of Pharmaceutical Assistants in 2017*<sup>11</sup>. It should be noted that all of the information provided to NARIC was provided by the PSI Executive and NARIC did not seek the input or experiences of the main stakeholders, Pharmaceutical Assistants, nor did they review notes of lectures, practical sessions, etc which are available from the Pharmaceutical Assistants Association.

The NARIC report is flawed in a number of ways:

- There is no comparison between examination papers of pharmaceutical assistants and pharmaceutical chemists (now called pharmacists) of the day. Currently there are 10 ‘pharmacists’ who qualified prior to 1959, who would have the same learning outcomes etc as pharmaceutical assistants, as observed in the Working Group Report, *“between 1890 and 1958, no individual distinct course was provided for the Pharmaceutical Assistants qualification”*<sup>12</sup>.
- Credit was not assigned for Recognition of Prior Learning (RPL) including 40 years of experiential learning
- It did not allow for the course outcomes, i.e. the fact that the qualification was designed to enable pharmaceutical assistants autonomously perform all the functions of a pharmacist in their temporary absence as soon as they passed the examination and registered with the Pharmaceutical Society of Ireland.

These aspects of the NARIC Report are not flagged in the Working Group Report. Instead the Working Group Report provides a value judgement on the job role of pharmaceutical assistants building a case for restrictions on the role by making inferences and in some instances providing misinformation, including:

- The Working Group Report states that *“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”*<sup>13</sup>. This is no evidence provided for this statement and as outlined there are currently ten pharmacists on the PSI register who undertook basically the same course as pharmaceutical assistants; 167 pharmacists who qualified prior to 1978 and completed a three year basic degree; numerous more pharmacists who completed a four year degree. In this way of thinking, there will be a gap between the level of qualification of all of these pharmacists and those of pharmacist who completed the current

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<sup>11</sup> page 38 Appendix Five. Executive Summary NARIC Report (June 2017) Working Group on Temporary Absence Report (April 2018)

<sup>12</sup> page 4 Working Group on Temporary Absence Report (April 2018)

<sup>13</sup> page 15 Working Group on Temporary Absence Report (April 2018)

five years Masters programme. However, the gap in the level of qualification can not be known unless measured and in the context of 30 years ago, how relevant is it. Level of qualification does not predetermine level of competency for the purpose of the current regulatory framework, as if it did all qualifications of 30 or 40 years ago would have to be revisited and re-evaluated in relation to current regulatory frameworks in every profession. This would be totally discriminatory as older people, like pharmaceutical assistants, would have restrictions based on their practice impacting on their ability to earn a livelihood.

- The Working Group Report states “*the fact that Pharmaceutical assistants have not undertaken CPD*”<sup>14</sup>. This is an untruth. The majority of pharmaceutical assistants, like pharmacists have, since qualifying, engaged in CPD, attending the same seminars as pharmacists for the past 30 years (see Appendix Three for case study). CPD was a condition set for pharmacists and pharmaceutical assistants by PSI for renewing registration each year (to register had to tick a box agreeing to undertake appropriate CPD). Whilst pharmaceutical assistants are not mandated to engage in CPD under the Pharmacy Act 2007, to maintain professional practice, they engage in CPD, side by side with pharmacists. It should also be noted that the core competency framework and structures for recording CPD for pharmacists have only been in place since 2013.

### **Concluding Remarks**

It is evident from the Working on Temporary Absence Report that the context within which the Working Group operated directed, shaped and constrained the range of possible choices and outcomes. The evidence used was cherry-picked and manipulated to build a case that supports the agenda of PSI, the construction of a group of highly skilled professionals, ‘pharmaceutical assistants’ as a serious risk to public safety. The outcome of presenting incomplete and false evidence can have catastrophic consequences, as illustrated in how a 16-word statement ‘*The British government has learned that Saddam Hussein recently sought significant quantities of uranium from Africa*’ which was incorrect but used by US President George W. Bush to build his case for invasion of Iraq in his annual ‘State of the Union’ address.

No attempt has been made by the Working Group, the majority of whom serve the PSI, to undertake an evidence based risk assessment or to consider ways, such as mandated CPD,

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<sup>14</sup> Page 23 Working Group on Temporary Absence Report (April 2018)

inclusion in the PSI core competency framework, practice review process and Fitness to Practice, of ensuring that every pharmaceutical assistant like every pharmacist is competent to undertake their work. Instead the recommendations focus on curtailing the nearly 130 year work practices of pharmaceutical assistants. The position taken in this report reflects the failure of the PSI to act on their responsibilities to ensure all of those registered by the PSI undertake appropriate CPD, are competent and fit to practice and in this way provide quality assurances of standards in pharmacy practice and support the development of pharmacy practice for the benefits of patients and the wider health system.

### **Recommendations for Rule Development**

- Pharmaceutical Assistants are mandated to undertake CPD as one of the criteria for re-registration each year and are subject to the PSI Core Competency Framework.
- Pharmaceutical Assistants are included in the quality assurance process, requiring them to undergo the Practice Review process that evaluates four competencies: clinical knowledge, gathering information process, patient management and education and communication skills.
- Pharmacists make a statutory declaration that in 'temporary absence', cover will be provided by the pharmaceutical assistant employed by the pharmacist who has demonstrated competencies in the four areas.

## Appendix One: Working Group membership

The position and background/experience of members of the working group set up assist in the development of Rules constituted under the provision of section 30 of the Pharmacy act 2007.

Organisation	Position and Background
Pharmaceutical Society of Ireland (PSI)	<ul style="list-style-type: none"> <li>• Mr. John Bryan, PSI Inspection and Enforcement Unit (ex Army),</li> <li>• Ms Damhnait Gaughan, PSI Education and Registration (B.Sc (Pharm) MPSI),</li> <li>• Joanne Kissane, PSI Council member (Superintendent pharmacist Lloyd’s Pharmacy),</li> <li>• Ann Sheehan, PSI Council member (Business Development Specialist Consultancy, worked as senior Marketing/Sales Executive with Shannon Aerospace/Lufthansa, member of boards of CORU Optical Registration Board and the Nursing and Midwifery Board of Ireland, studying for degree in psychology).</li> <li>• Georgina Farren, co-opted by PSI (registered midwife and barrister, Midwifery Project Officer, Nursing and Midwifery Board of Ireland)</li> </ul>
Pharmaceutical Assistants Association (PAA)	<ul style="list-style-type: none"> <li>• Rita O’Brien, chairperson PAA (Pharmaceutical assistant, lecturer in DIT pharmacy technician course)</li> </ul>

## **Appendix Two: Survey of Work Practices of Pharmaceutical Assistants (2014)**

In 2014, the PAA undertook a survey of the work practices of pharmaceutical assistants. Two hundred and five pharmaceutical assistants responded to the questionnaire. The responses were analysed using SPSS. The survey found that in 2014:

- 60 per cent of respondents worked 15 to 30 hours per week, 25 per cent worked over 30 hours and 15 per cent worked less than 15 hours per week, usually one day a week in a pharmacy they have worked in for years.
- The majority, 77 per cent worked in one pharmacy, and have done for numerous years, the mean number of years being 18 years.
- 94 per cent of respondents were permanently employed in the pharmacies they worked in
- All covered the pharmacist's day off and other short absences including lunch hour and meetings. A majority also covered the pharmacist's holidays as agreed under the 1994 Code of Practice.

### Appendix Three: A Case Study of Pharmaceutical Assistant’s Engagement in CPD.

This case study outlines the real world experience of pharmaceutical assistants in relation to maintaining professional competencies through engagement in CPD. Pharmaceutical assistant A has worked in Pharmacy C for 21 hours per week for 15 years and covers pharmacist B’s day off, lunch breaks, late nights and holidays. Pharmaceutical assistant A and pharmacist B attended together over the last 4 years the CPD courses listed below.

Course Name	Event Name
An Update on Oral Chemotherapy Agents (Autumn 2013)	Oral Chemotherapy
Drug Interactions	Drug Interactions
An Update on the Management of Pain	Pain Management
A Review of Insulin Therapy	Insulin Therapy
An Overview of Common Neurodegenerative Conditions	Neurodegenerative Conditions
Management of Common Ear, Nose and Throat Conditions	Management of ENT
The Use of Antimicrobials in the Community	Antimicrobials
Dermatology: Acne and Psoriasis	Dermatology: Acne and Psoriasis
The Management of Inflammatory Bowel Disease	The Management of Inflammatory Bowel Disease
Depression	Depression
Liver Disease	Liver Disease
Ischaemic Heart Disease – The Patient Journey	Ischaemic Heart Disease - The Patient Journey
Dermatology: Dry Skin and Eczema	Dermatology: Dry Skin and Eczema
Schizophrenia – An Update	Schizophrenia - An Update
Iron Regulation: Anaemia and Haemochromatosis	Iron Regulation: Anaemia and Haemochromatosis
Management of Allergies	Management of Allergies
An Update on Oral Chemotherapy Agents (Spring 2017)	An Update on Oral Chemotherapy Agents
Update on Drug Interactions and Adverse Drug Reactions	Update on Drug Interactions and Adverse Drug Reactions
Medication Safety in Your Practice	Medication Safety in Your Practice
Diabetes in Practice	Diabetes in Practice
Chronic Obstructive Pulmonary Disease	Chronic Obstructive Pulmonary Disease
Cancer Management – Supportive Medicines	Cancer Management - Supportive Medicines
Clinical Skills for Community Pharmacists	Clinical Skills for Community Pharmacists
Atrial Fibrillation	Atrial Fibrillation
Dyslipidaemia	Dyslipidaemia