2018

Report of the Expert Group

ON THE DRAFT PHARMACEUTICAL SOCIETY OF IRELAND (TEMPORARY ABSENCE OF PHARMACIST FROM PHARMACY) RULES 2018

REPORT SUBMITTED TO THE PHARMACEUTICAL SOCIETY OF IRELAND ON 5 DECEMBER, 2018

Report of the expert group on the appropriateness of the duties that a pharmaceutical assistant may perform during the absence of the pharmacist held on 20th November 2018

Members present:

- Kieran Ryan (Chair)
- Ronan Quirke
- Nicola Tyers (Report writer)

In attendance:

- John Bryan
- Damhnait Gaughan
- Siobhan Fitzgerald (Minute taker)

Declaration of interest

Ronan declared that he had for 18 years worked alongside a Pharmaceutical Assistant who retired (and for no other reason).

Background

Background information (appendix 1) had been provided to the Expert Group (hereafter known as the 'Group') and this covered the Pharmaceutical Society of Ireland (PSI) Council papers, the report from the Working Group, reports from the Pharmaceutical Assistants' Association (PAA), the public consultations, draft rules and requirements of this Expert Group (based on a range of expertise as outlined in appendix 2). It was reported that the draft rules had been agreed by Council in 2018 and now the Group was being asked to consider rule 8 relating to the tasks that a Pharmaceutical Assistant (PA) may perform due to a potential weakness in the drafting mechanism used.

The principles of Better Regulation were referred to in ensuring that a decision is based on these factors as listed below:

- Necessary
- Effective
- Proportionate
- Transparent
- Accountable
- Consistent

The Group discussed the background to the evolution of the draft rules for temporary absence that formed the basis of the work of this meeting and clarified why the challenge had arisen to the drafting mechanism.

Discussion

The timeline of the process in developing the temporary absence of pharmacist from pharmacy rules 2018 was discussed and a summary of the process that the Working Group on temporary absence went through was reported. The Working Group had developed a matrix of the roles that PAs could safely carry out in the absence of a pharmacist which can be found in appendix 7 of the Working Group report. It was reported that when considering these roles the Working Group had identified what tasks needed to be reserved for a pharmacist based on potential risk, what other professions had developed and the benchmarking of qualifications. In the absence of Quality and Qualifications Ireland agreeing to assess the PA qualification it is important to note that NARIC (The National

Recognition Information Centre for the United Kingdom) did not make a statement on the mapping to the Irish system. What can be noted is that in the UK up to 1967 the diploma of Pharmaceutical Chemist was at level 5 and thereafter Degrees of Bachelor of Pharmacy were awarded at level 6. It is likely that the Irish qualification was targeted at a similar level. Discussion about the level of qualification ensued and it was noted that it is likely that there was a difference of two academic levels at the time that the PA qualification was awarded and this is consistent with the different roles. This difference in role at registration reflected the level of attainment of knowledge, skills and competence, especially in relation to making judgements. It was noted that the level of qualification changes over time – the contemporaneous standard, and continuing competence is achieved through continuing professional development. Although this was not a requirement for either profession for many years, it is recognised that this professional activity is central to ensuring continued competence.

A point was made that the experience gained from working in a role (especially as a member of a team) for a long period meant that the professional became an expert in that role (also known as expert generalist). This has resulted in a group of Pharmacist Assistants that are experts in their role and the Group recognised their input. The report on Supervision in Community Pharmacy (2013) highlights the expert technical role that pharmacy staff perform whilst also identifying safe, borderline and unsafe activities that can be carried out in relation to supervision and accountability, considering this in the context of temporary absence of a pharmacist. PAs have been able to enact their role in the absence of boundaries for many years, which would appear to be an omission and then in 1994 an agreement was made between the then PSI and Pharmaceutical Assistants' Association. This does not however address the PA scope of practice, but does suggest they can carry out the pharmacist's role in their absence, which could be for up to two weeks at a time. The culpability of pharmacy members within the pharmacy team was then discussed and it was highlighted that no individual is responsible for the personal acts or omissions (outside of the governance in place) of someone else and thus although a PA may be an expert in technical aspects they need to operate within the framework of competence. This once again linked back to defining what the scope of practice for a PA is.

Discussion then explored whether PAs want to be brought under regulatory powers and the evidence from the consultation highlights that PAs as a group want this. The case is specifically made by the PAA in relation to Continuing Professional Development (CPD) and Fitness to Practice (FTP) – and not needing any additional legislation to ensure this. This does not however address the gap in the level of qualification or scope of practice. On exploring whether CPD and FTP could be articulated for PAs, it was noted that this would need a change in the primary legislation that gives the PSI the power to act. The 2007 Act under 7 (2) (b) (i) does allow the PSI to conduct inquiries however there is no power to impose sanctions, thus preventing the Society from enforcing FTP on PAs. As this is not enforceable then no cases have been developed and hence no reports of any PA's lack of fitness have been reported, thus nothing is available to evidence the FTP failings of what is likely to be a minority of outliers (as for pharmacists) of this professional group. Also it is important to note that the 1994 agreement is not an agreement in statute and so not enforceable. There is a similar argument around CPD where pharmacist obligations are specifically mentioned in the Act under 7 (1) (d) although all registrants are asked to tick a box declaring CPD is undertaken on annual registration.

As the PSI had determined that powers regarding ensuring FTP and CPD are undertaken for PAs are not feasible under the Act, then defining rules under Section 30 were considered in addressing the scope of practice of this professional group. It was reported that Council had made this decision

previously and embarked on the route to develop rules around Section 30 and also to consult with a wide range of stakeholders including the PAs themselves and members of the public.

There was discussion around how the public can identify a PA from a pharmacist and the importance of this. It was noted that the PSI had a role in this to explain to the public the roles of the pharmacy team and how this operates in community pharmacy. As the Act states that a pharmacist is in personal control then what are the requirements around Section 30 that would meet public perceptions as well as ensure patient safety? Although PAs appear happy to be brought under regulatory powers, it appears to be specifically around CPD and FTP, which are routes of regulation that are not enforceable (and would need primary legislation to change). The consultations on temporary absence in both 2016 and 2018 show that PAs question using Section 30 to address the scope of practice, although it can be seen from the Pharmacy Act that this legislation does need rules to provide all levels with a framework on how temporary absence is to operate.

Consideration of draft rule 8

Given the difference in level of qualification of PAs then the absence of a scope of practice (also referred to as a task list) was considered as being at odds with the regulatory landscape and not consistent with the Pharmacy Act 2007, thus this needed to be defined in rules and was addressed by discussing each aspect of rule 8.

Activities which may be carried out by pharmaceutical assistant when acting on behalf of pharmacist

8.(1)When acting on behalf of a registered pharmacist during the temporary absence of the registered pharmacist, a registered pharmaceutical assistant may carry out the following in addition to his or her normal activities as a registered pharmaceutical assistant:

a) dispensing a repeatable prescription where:

(i) it is not the first dispensing of the prescription, and

(ii) the prescription is for medicinal products other than—
  (I) high tech products,
  (II) cytotoxic medicinal products, and
  (III) narrow therapeutic index medications;

b) dispensing, or providing by sale or supply, pharmacy-only medicinal products and general sale medicinal products; and

c) supervising the sale or supply of pharmacy-only medicinal products and general sale medicinal products

The description of 8 **(1) a) (i)** (dispensing a repeatable prescription where this is not the first dispensing) was considered reasonable insofar as it is usually where there is a higher risk to patient safety and the prescription is assessed for clinical appropriateness and use of medication in pre-existing morbidities as well as its use with other medication is considered. This is not a technical aspect, but rather one that requires judgement based on knowledge and skills. The case of a 'simple' antibiotic was raised, however it would be difficult to identify when a range of antibiotics were safe or not without getting into a defining a list of what could be used and when. Based upon this discussion, on balance it was considered that this description of the role was reasonable.

The products listed in **8(1) a) (ii)** (excluded from a repeatable prescription) were considered with **(I) (high tech products)** being a service commissioned by the Health Service Executive where pharmacists are paid for a consultation and share their clinical knowledge and expertise – this is a distinction from other dispensing and is where a pharmacist is the care provider. This section was considered as being reasonable based on the pharmacist being considered the care provider. It was

also agreed that **cytotoxic medicinal products (II)** were high risk medicines and as such should be reserved for pharmacist oversight, as regimes could change and the margin for error was also a risk. **Narrow therapeutic index medicines (III)** were then considered and discussion focused around what are these defined as? In a patient with renal failure this may be different from a patient with liver disease for example. Whilst the Group agreed with the principle that those with a smaller margin for drug dosing error was what was intended, they advised that the PSI should consider providing guidance around what a may constitute a narrow therapeutic index medicine.

The Group then considered **8 (1) (b- dispensing/providing) and (c -supervising)** the sale or supply of pharmacy-only and general sale medicinal products – and considered this to be enabling and reasonable.

The Group then considered the scope of rule 8 against the principles of Better Regulation:

- Necessary – to date there has been no description of the scope of practice of a PA, which is a different level of qualification from a pharmacist, but in the temporary absence of a pharmacist (sometimes for up to 2 weeks) appears to enact the same role. The Group considered that undertaking the role as described in the 1994 agreement (prior to the Pharmacy Act 2007) for a long period of time is at odds to the pharmacist being in personal control of a pharmacy and needs a clear description of the scope of practice.
- Effective – the rules in relation to the scope of practice are clear on the boundaries of what constitutes good patient care. Should the rules be enacted then the PSI will need to ensure compliance and enforcement.
- Proportionate – the advantages of describing a clear scope of practice are that patient safety will be prioritised thus prioritising patient care. The professional group of PAs will however need supporting in how this is enacted as the scope has been undefined for many years. Potential resource issues will also need to be explored both for the PAs and for those operating the pharmacy (in relation to finances and availability of staff, especially in remote areas).
- Transparent – the PSI has gone through a process that has listened to a wide range of stakeholders (including the PAs) and has also utilised experts. Guidance from the PSI in relation to the PA role and how the public identifies the respective roles will be beneficial.
- Accountable – the rules will describe clear lines of accountability between the PAs and the pharmacist regarding their respective roles.
- Consistent – these rules will allow for consistency in how the role of PA is undertaken. Previously there had been no clarification of the scope of practice thus resulting in an anomaly.

The Group made a number of observations in the context of the rules as a whole and these included:

  - Rural pharmacy locations where it can be very difficult to get a pharmacist locum for an extended period of time.
  - The role of an experienced employed PA compared to a locum in providing continuity of service to patients in the temporary absence of a pharmacist.
  - The availability of pharmacist locums
  - The human rights (in relation to the right to work and gender) of Pharmacist Assistants who have operated for many years without a scope of practice and thus may have current roles amended
  - A pragmatic guidance on how the public could be made aware of the roles of staff in a pharmacy through identification of Pharmacist, PA, Shop Assistant, Technician etc.

- Providing guidance on narrow therapeutic index medicines
- Notwithstanding the legislative issue of compelling PAs to fall under CPD and FTP, could guidance outlining the expectations of PAs in fulfilling requirements to maintain these aspects be provided
- Guidance be provided by the PSI with respect to the expectation on pharmacists in delegating duties of supervision in the period of temporary absence.

The Group supported the scope of practice described in the draft rule 8 and recommends accordingly in line with the terms of reference of this Group.

Appendix 1

Papers Provided to the Expert Group

- Terms of Reference of Expert Group on the assessment of the appropriateness of the duties that a pharmaceutical assistant may perform during the absence of the pharmacist

- Draft Pharmaceutical Society of Ireland Temporary Absence of a Pharmacist from Pharmacy Rules 2018

- Benchmarking the Pharmaceutical Society of Ireland's Legacy Qualification (2017), UK NARIC Benchmarking Report

- Working Group on Temporary Absence Report 2018

- Shadow Report on the PSI Working Group on Temporary Absence (April 2018), the Pharmaceutical Assistants Association

- Human Rights and Equality Impact Assessment of the Proposed Draft Pharmaceutical Society of Ireland Temporary Absence of a Pharmacist from Pharmacy Rules Report 2018 by the Pharmaceutical Assistants Association

- Pharmaceutical Assistants Association Chairpersons Address to Council (23/3/2017)

- Supervision in Community Pharmacy (2013), Bradley F., Schafheutle E.I., Willis S.C. & Noyce P.R. https://pharmacyresearchuk.org/wp-content/uploads/2014/01/Supervision-in-Community-Pharmacy-Full-Report-070114.pdf

- Public Consultation on Pharmaceutical Society of Ireland (Temporary Absence of a Pharmacist from a Pharmacy)
  Rules 2018 https://www.thepsi.ie/Libraries/Consultations/Consultation_Report-Temporary_Absence_of_a_Pharmacist_from_a_Pharmacy_2018.sflb.ashx

- Public Consultation on draft Pharmaceutical Society of Ireland (Regulation of Temporary Absence Cover by Pharmaceutical Assistants) Rules 2016
  https://www.thepsi.ie/Libraries/Consultations/Temporary_Absence_Public_Consultation_Report_2016.sflb.ashx

Appendix 2

Expertise of members of the Expert Group:

Ronan Quirke is a community pharmacist in Clonmel and has worked in community pharmacy for over 18 years; prior to that he was a hospital pharmacist in Dublin and the UK. He is a Senior Lecturer in the School of Pharmacy, University College Cork and an Adjunct Assistant Professor at the School of Pharmacy, Trinity College. He is the Alternate Chair of the Professional Conduct Committee of the PSI and was appointed by the Minister for Health to the Advisory Committee on Human Medicines at the Health Products Regulatory Authority. Previously, he has served as a Council Member of the PSI and was PSI President from 2005-2007. He is a former Chair of the Accreditation Committee for the Irish Schools of Pharmacy for the PSI and also served as Secretary of the Hospital Pharmacists Association of Ireland.

Nicola Tyers is a Pharmacist who has over 25 years of experience and is Director of the Pharmacy Training Company. Having previously worked at the GPhC as Head of Pre-registration and also for the previous regulator, the Royal Pharmaceutical Society (RPS) of Great Britain she has a deep understanding of regulation and the support system that registrants need. Regulatory work has included oversight and responsibility in Great Britain for first entry to the register (good character, health and performance), registration appeals, pre-registration tutors, pre-registration training sites, the registration assessment, annual membership of the register, input into the Pharmacy Order 2010, as well as input into the PSI's training requirements around emergency medicines and vaccinations training.
Previous roles include lecturing in Pharmacy in the academic sector in both Great Britain (currently within University College London and Medway School of Pharmacy as an external speaker) and New Zealand leading in pharmacy practice, experience of working within community pharmacy (in Eire, New Zealand and Great Britain), primary care settings and with pharmaceutical companies. Having developed on online learning resource for pre-registration tutors, Nicola has been working closely with NHS Education for Scotland and Health Education England to help develop tutors that are fit for purpose. Recent work has included working with a range of stakeholders including community pharmacies (pharmacists, technicians and counter staff) and pharmaceutical companies to develop novel services including training, having recently presented at Pfizer's National Hospital Pharmacy Forum.

Other current roles include being a Member of the Pharmaceutical Society of Ireland Accreditation Panel, Lay Member for Patient and Public Involvement at Medway CCG – a governance role, which also involves chairing and working closely with patients and members of GP Patient Participation Group, and is a member of the organising committee for West Kent and Medway RPS Local Practice Forum.

Kieran Ryan was appointed as Managing Director of Surgical Affairs at RCSI in August 2016. He is responsible for the development and implementation of the strategic direction for the Department of Surgical Affairs. Core to this brief is the delivery of our National Surgical Training Programmes, engagement with our Fellows and Members and specialty groups, promoting RCSI as a world leader in surgical training and medical education and provision of greater support and input to surgical practice. Kieran, as a member of the Senior Management Team, also supports our postgraduate faculties in delivering their remit and strategic objectives.

Prior to joining RCSI, Kieran was Chief Executive Officer of the Irish College of General Practitioners, a post he held since 2011. Prior to this, Kieran worked with the RCSI Department of Surgical Affairs as Research Manager and then Associate Director. He brings with him a wealth of experience and his expertise across the many facets of the healthcare ecosystem having previously worked as Head of

Clinical Services in the Hermitage Medical Clinic, Head of Healthcare Practice at Aon Risk Services, GCP inspector with the Irish Medicines Board (now HPRA), Clinical Trials Manager with GSK as well as other clinical research roles with Covance CAPs and ICON.

Kieran holds a BSc (applied) in Chemistry and Mathematics from Kevin Street DIT and Trinity College Dublin, a MSc in Healthcare Ethics and Law and MSc in Healthcare Leadership and Management Development from RCSI.