PSI Consultation on the

Pharmaceutical Society of Ireland (Temporary Absence of Pharmacist from Pharmacy) Rules 2018

Submission

from the

Pharmaceutical Assistants Association (PAA)

August 2018

Introduction

The PSI's draft rules are fundamentally flawed.

There is no clinical evidence to support the proposed rule changes.

The cost implications and societal and operational impacts have not been addressed by the PSI never mind quantified.

The acquired rights and legitimate expectations of the 336 registered pharmaceutical assistants (PAs) affected by the proposed rule changes have been ignored, as have their workplace rights.

Due to the absence of evidence-based research to justify any change to the status quo and the false premises upon which the PSI bases its proposals, the PAA submits that the Statutory Instrument should be withdrawn.

At the heart of the situation is that the Government decided not to regulate PAs in the Pharmacy Act 2007. Retrofitting that mistake by means of a Statutory Instrument is not the solution.

The PAA would like to enter into a constructive dialogue with the PSI, without pre-conditions, before any rules are adopted to find solutions that are relevant, workable and 'fit for purpose'.

This submission seeks to explain in more detail the precise reasons for this recommended course of action.

Impacts

At the outset, our views on the expected impacts of the proposed rule change are highlighted.

Expected Impacts

1. PAs would not be allowed to dispense, even when a pharmacist is on the premises.
2. As a consequence, many pharmacies especially in rural areas would have to close.
3. The jobs of many of the current cohort of PAs would be jeopardised.
4. The PA's professional qualifications would be down-graded.
5. Workplace practices in all pharmacies employing PAs would change.
6. Some pharmacies would be forced to operate reduced hours.
7. Cost of compensation and redundancies to the State and pharmacists.

The PSI failed to identify any impacts.

The PSI should quantify the impacts identified by the PAA and be satisfied that the costs and operational changes are reasonable and proportionate to the actual clinical risks they are seeking to mitigate.

Impact from the perspective of the experts – pharmacists and pharmaceutical assistants

In the absence of evidence based decision-making in the formulation of these proposed rules by the PSI Working Group on Temporary Absence, the PAA commissioned their own research on the impact of the proposed rules on the pharmacy industry and public health and safety (the full reports will be launched mid September). The preliminary findings from the research, a survey undertaken with pharmacists and one undertaken with pharmaceutical assistants, indicate that:

1. Pharmacy services will be reduced, particularly in rural areas

- Of the 130 pharmacists who completed the online survey, 77% agreed that it will be difficult to maintain the current service they provide if the proposed rules are implemented, 17% are uncertain as to how their service will be impacted.
- These pharmacists depend on their pharmaceutical assistant to provide temporary absence cover for their holidays (59%), lunch hour (57%), pharmacist's day off (85%), late nights (10%), other leave such as illness, meetings, funerals, childcare emergencies (67%).
- Independent rural pharmacies will be proportionately more impacted than pharmacy chains and independent pharmacies in urban areas as explained by these pharmacists working in towns with population of 5000 or less

"*My qualified assistant has worked with us for 26 years and has always been highly professional in her work keeping up with developments. She is extremely capable. We have great difficulty in obtaining pharmacist relief, as the younger pharmacist prefers an urban workplace. If my workload increased I would strongly have to consider putting my pharmacy up for sale or failing that closing which would impact on the local community especially as our local GP has recently retired and his practice is looked after by A GP practice in the nearest town which is over 20Km away"*

"*It is not possible to get locum cover so if the pharmaceutical assistant can't cover I may have to remain closed some Saturdays. Major impact on my business...Major implications for my work/life balance. It's fairly disastrous for pharmacy in Ireland"*

"*May have to close one pharmacy*"

"We find it hard to find a pharmacist to work in a small independent pharmacy"

"It will be necessary to reduce our opening hours – which will have an impact on patient care"

2. Jobs will be lost

- 76% of pharmacist respondents who currently employ a pharmaceutical assistant will not be in a position to do so if their pharmaceutical assistant can only cover 1 hour in temporary absence and be restricted in what they can dispense, 17% will have to review their situation. Once again it will be smaller independent pharmacies that will be impacted most, with 40% of respondents working in pharmacy chains disagreeing or neither agreeing or disagreeing with the proposition that they will no longer be in a position to employ pharmaceutical assistant compared to 23% of independent community pharmacies.

"*It is the end of my personal life, my family life will suffer immeasurably as I will have work 13 hours extra per week.. I will no longer be able to pop to the bank or a funeral or collect my kids from school or watch their football match ….. I will be a prisoner at work from 9am to 6pm every day…it is the most unfair proposal I have every seen, my assistant is more use and better than any pharmacist I have ever employed"* (independent pharmacy in town with population of 5000 or less)

- Of the 140, pharmaceutical assistants surveyed, 75% cited the loss of their jobs as an outcome of implementing the PSI proposed rules.

"*I will lose my job as I I work for a small independent pharmacy who will not be in a position to employ another pharmacist to provide cover*"

"*My services would no longer be required as I would not be able to cover for my employer. I am a widow with 10 more years on my mortgage. I would become unemployable"*

"My job will be gone and I'll be replaced by a pharmacist"

3. Pharmaceutical assistant's qualification will be downgraded

- 98% of pharmaceutical assistants surveyed will no longer be able to undertake the unique role they are qualified to do "perform the duties of the pharmacist in his temporary absence", making them unemployable as these pharmaceutical assistants explain:

"will make me unemployable .. if I couldn't perform normal duties as a Pharmaceutical Assistant … why would they keep me"

"*My services would no longer be required as I would not be able to cover for my employer. I am a widow with 10 more years on my mortgage. I would become unemployable".*

I will now be of no benefit to my pharmacist, he will have to employ another pharmacist which for an independent pharmacy would be expensive, and will result in loss of days/ hours for me"

- 98% of pharmaceutical assistants surveyed believe their qualification will be worthless. From discussion with their employers, to remain working they will be downgraded to technician, counter-hand, administration, reducing their income by nearly half as outlined by these pharmaceutical assistants.

"*My understanding is that I can remain working as a technician, clearly with a reduction in my income*"

"I think my work at very best will be downgraded to technician work or just administration paperwork e.g. GMS returns with rates of pay reduced to match"

"*My employer will no longer hold me on my present rate of pay, as basically I will be no more than an "unqualified" technician. My personal financial situation will be untenable as I have mortgage repayments based on my present income"*

4. The proposed rules if implemented will impact on patient care and pose health and safety risks to patients.

- Majority of pharmacists(60%) working in pharmacies that employ pharmaceutical assistant already work at least 40 hours with 20% of these working 50 hours or more.
- Findings from the survey show that 83% of pharmacists will have to increase the number of hours they already work if the registered pharmaceutical assistant qualified to dispense medication in their temporary absence and hugely experienced (70% of the 140 pharmaceutical assistants survey have between 35 and 41 years experience) can not no longer do so. These pharmacist respondents sum up the impact the loss of this qualified and experienced manpower will have:

"*At a time when pharmacist numbers are critically low in terms of realistic availability, the undoubted and well acknowledged impact of Brexit to add further stress to those same numbers, the PSI are astonishingly trying to remove the role of Pharmaceutical assistant by default thereby decreasing the numbers of qualified, experienced and professional people by about 300. The role of the PSI, as laid down in the code of conduct for pharmacist is about patient care. this move would only diminish patient care and to a considerable level*"

"This potential change is ill thought out, it will create problems within pharmacies and will not improve patient care. There is a manpower problem within community pharmacy, we cannot get enough pharmacists. Existing community pharmacists working longer hours will disimprove patient safety"

"*Implementing this rule change without an increase supply of available pharmacists to cover shortfalls will cause huge problems in the industry. There is an increase in pharmacists on the register but this is not translating into an increase in pharmacists available to work. This ill thought out measure will exacerbate and already difficult situation*"

"*The proposed changes will also lead to a major pharmacist supply problem as the availability is currently not there as things stand. Likewise the standard of Locum*

pharmacists is not to the standard required (language, experience etc) and the profession is better served by leaving things as they currently stand"

"Putting more strain on the pharmacy industry, it is at tipping point already. What is the alternative? Hiring newly qualified pharmacists that have way less experience and .. twice as likely to make mistakes hindering patient safety"

"I will be losing a highly competent and committed staff member who has been an integral part of my pharmacy's development…I will have to work longer hours and employ the services of locums that neither I nor my customers know or trust to the same level as my PA"

5. Cost of the impact of the proposed rules on pharmacies and tax payers

- 80% of pharmacist surveyed agreed that their pharmacy business would incur additional costs, 15% were uncertain and only 5% disagreed there would be extra costs involved. This pharmacist provides an example of these costs

"The locum situation in Named Counties this summer has been ridiculous, The rate per hour being demanded before a locum accepts a days work has forced pharmacy businesses to incur massive additional staff costs this summer…. Pharmacy is under massive changes and taking away staff members that have been at the forefront for the growth of the business will have untold implications for the trade"

- Cost of redundancy to pharmacist will be substantial considering that in this survey of 130 pharmacists, 76% of pharmacists will no longer be in a position to employ a pharmaceutical assistant if the proposed rules implemented. Almost half of the 140 pharmaceutical assistants who completed survey (49%) have worked over 20 years in the same pharmacy and 29% have worked 10 to 20 years in the same pharmacy, with 81% work 16 hours or more, the majority (58%) work between 16 and 30 hours on average. The tax payer will be required to foot the bill for compensation for loss of livelihood which will be substantial, as over half of current pharmaceutical assistants still have another at least 7 years before being eligible for the State pension (estimated cost over €42 million[1]). This pharmacist points to the cost

"*I may have to decide to seek a compensation claim from the PSI for the cost of redundancy if the new retrospective regulation comes in to force. This claim among all the pharmacies involved could have serious financial impact on the PSI"*

The PSI's Approach to Decision-Making

The approach undertaken by the PSI's six member working group under the auspices of the Registration and Qualification Recognition Committee in considering the drafting of rules under Section 30 of the Pharmacy Act 2007 was amateurish at best, certainly partisan in its approach and fell well short of the professional standards expected of a regulatory statutory body.

[1] PA working 30 hours per week, average salary €40000

The PAA has published an assessment of the flaws and weaknesses of the supposedly deliberative approach and requests (again) that its analysis be published so as to give survey respondents and wider stakeholders a fully picture of what actually happened.[2]

The main areas of concern to the PAA and its members are as follows:

1. A cursory attitude was adopted; so much so that decisions on the complex issue of what constitutes 'temporary absence' was made in the first two hours of deliberation (out of a total of just ten hours of meetings). Specifically, the decision of the working group to define temporary absence to one hour per day was not based on any evidence, nor a detailed assessment of clinical risk impacts.
2. The working group failed dismally to respect Government guidelines on the preparation of changes to the regulatory arrangements that will have a negative impact of PA's careers, qualifications and job prospects. The impacts of the proposed rule changes have not be presented.
3. The PSI's recommendations are based on value judgements, perceptions and a negative view of the contribution that PAs can make to the pharmacy profession.
4. The PSI failed to carry out an assessment of PA's roles and responsibilities based on benchmark data from comparable countries (such as the Netherlands).

As a public body the PSI has a duty to be measured, balanced and genuine with the ultimate aim of leading to the profession it regulates better outcomes and greater understanding of the benefits and consequences of all its proposed actions.

Against this background, we submit that the PSI should therefore re-consider the robustness of the evidence that has informed its approach to temporary absence issue to date.

Drivers for Change

The PSI identified five main reasons, as follow, why the rule changes were deemed necessary:

- The qualification of PAs was 'considerably below' the qualification of registered pharmacists.
- Unlike pharmacists, PAs are not required by law to undertake continuous professional development (CPD).
- Unlike pharmacists, PAs are not subject to fitness to practice.
- The changing face of pharmacy practice, including a significant increase in the use of high-tech medicines.
- A rule change was justified on the basis of the risk assessment undertaken.

As the PSI's staring point is grounded on its understanding of these issues, each are addressed hereunder in turn.

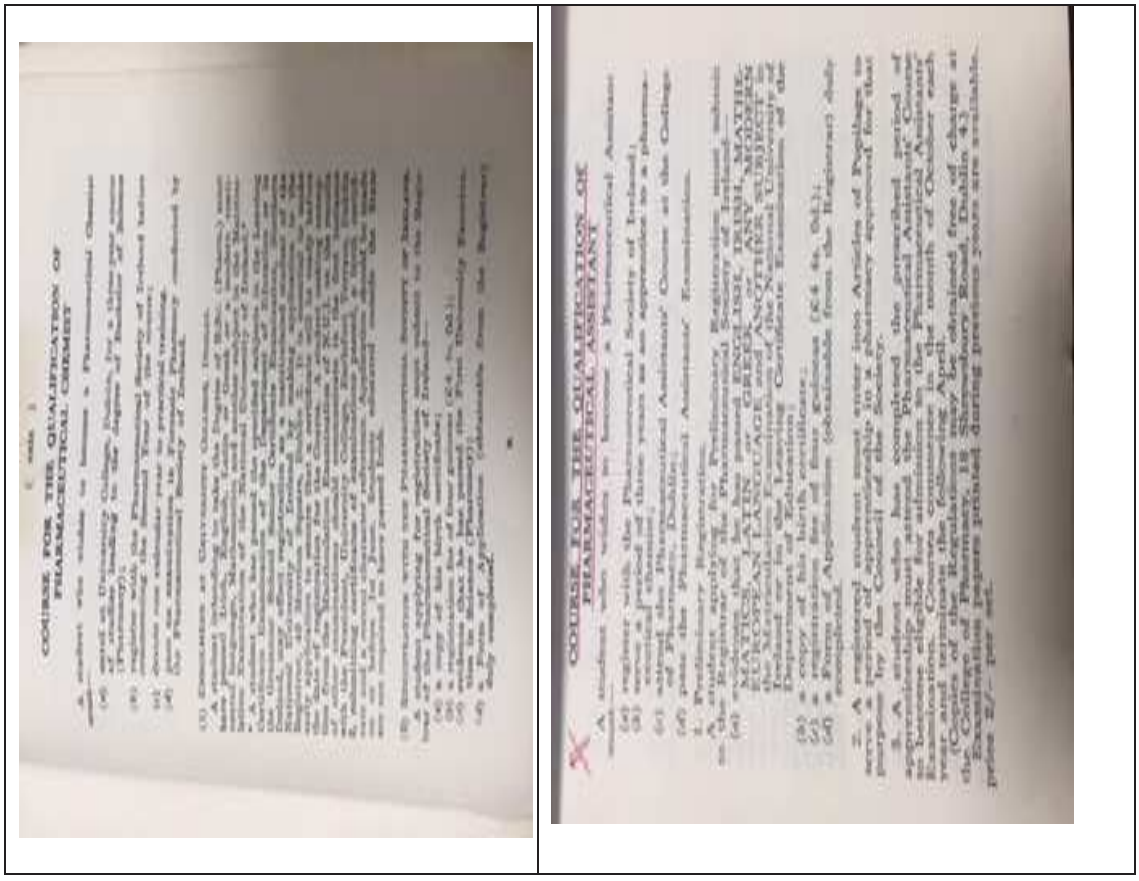
[2] Pharmaceutical Assistants Association,*Shadow Report on the PSI Working Group on Temporary Absence Report* (April 2018), June 2018.

Professional Qualifications

The majority of the current cohort of PAs completed their professional qualifications during the 1970s.

The PSI asserts, using the NARIC study as the base for its views, that the course for the qualification of a PA is the equivalent of the Leaving Certificate. As the Leaving Certificate was the entry requirement to get on the course in the first place, this finding is wrong in fact and in substance.

Hereunder are the prevailing guidelines (1970) for this course as well as the course for the qualification of pharmaceutical chemists.



Source: The Calendar of the Pharmaceutical Society of Ireland (1970)

The entry requirements for both course were the same i.e. Leaving Certificate.

PAs had to spend three years in an apprenticeship arrangement before they qualified. Chemists only had to get a year's practical training.

Both PAs and chemists were qualified to dispense medicines.

In a fundamental manner, the PSI appears to ignore this critical matter as it is suggesting, should the rule change be implemented , that PAs would no longer be able to perform this core task in every pharmacy.

In addition, the PSI did not ask the NARIC researchers to assess the impact of thirty to over forty years in-pharmacy experience accumulated by PAs. The principle of Recognition of Prior Learning should have been factored into the assessment.

Basing a rule change on an assessment of a professional qualification dating back to the 1970s is misleading as it ignores the significant practical experience that PAs have garnered over the past forty years.

CPD/Fitness to Practice

PAA survey of PAs indicates that the majority of PAs engage in CPD, keeping abreast of relevant advances in scientific and technical progress and clinical practice in many ways

- 96% of respondents read journal articles, updates from Irish Medicine Board, information leaflets on new medication; other sources referred to included Medscape, in-house education events.
- 76% participate in IPU academy learning events and/or Irish Institute of Pharmacy learning events;

The PAA would be quite happy for PAs to be covered by mandatory CPD arrangements and a robust Fitness to Practice requirement. It is the view of PAA and IPU that mandatory CPD could be achieved through an amendment to Health and Social Care Professionals Act 2005 This Act has been amended over the years to make all healthcare professionals as defined under the Health Identifiers Act 2014 except pharmaceutical assistants subject to mandatory CPD.

PAs would have no issue complying with the PSI core competency framework for pharmacists as this is a much better solution than the proposed professional task list.

While some of these proposals would require an amendment to the Pharmacy Act 2007, the PAA is open to working with the PSI to produce operational guidelines in the meantime.

In addition, the PAA is willing to engage in a constructive manner with the Irish Institute of Pharmacy.

The Changing Face of Pharmacy

In drafting its proposed rule changes, the PSI made no reference to its report (November 2016) *Future Pharmacy Practice in Ireland: Meeting Patients' Needs.* While this report did not specifically examine the potential role and contribution of PAs, it is clear that this professional group will be required to play its part in the delivery of the ambitions and tasks identified.

There are several important statements, as follows, in the strategy document relevant to PAs (and the proposed rule changes).

1. There should be a focus on patient safety based on making the best use of pharmacists' expertise.
2. The profession (that includes PAs) 'has a critical role to play within the healthcare system.'
3. Due consideration should be given to the effective deployment of the pharmacy workforce.
4. The role of pharmacists (and PAs) includes the delivery of national information and awareness campaigns, prevention and early intervention initiatives, screening services as well as initiatives supporting and empowering people to look after their own health and wellbeing.
5. There should be a greater delegation of operational roles to trained staff members.
6. The pharmacist (and PA) has a role to counsel patients in the supply of non-prescription medicines.
7. The pharmacist's potential (and indeed that of PAs) is under-utilised.

The PSI needs to explain to the PAA how its members are expected to contribute to the achievement of the PSI's strategy as set out in the November 2016 report.

Risk Assessment

It is best practice in making regulations that all changes proposed are based on evidence.

The PSI indicated that a risk assessment was undertaken of the work that could be undertaken by a PA in relation to risk to patient safety 'of using persons with limited qualifications to undertake the full range of tasks undertaken by a registered pharmacist.'[3]

No such risk assessment was in fact carried out. In reality, some members of the working group came to significant conclusions based on personal views and perceptions rather than considering risk-based evidence data.

There is no clinical evidence to hand to justify the PSI conclusion that PAs should no longer be allowed to dispense medicines.For example, the PSI Preliminary Proceedings Committee Annual Reports make no reference to complaints against PAs.

Therefore the PSI should justify the disproportionate nature of its proposal to ban PAs from dispensing medicines.

Better Regulation

In its report that allegedly supports the rule changes, the PSI attaches - quite correctly - huge significance to the principles of regulatory change as articulated in the Government's (2004) White Paper on Better Regulation.

[3]page 23 of the Report of the Working Group on Temporary Absence.

The PAA submits that the PSI has failed to meet all the basic five tests/principles that must be proven and satisfied before significant regulatory change is considered.

Necessity: Instance of clinical negligence affecting patient safety as been more prevalent among PAs has not been reported what is the justification for the proposed rule change?

On the contrary, evidence from the PAA survey of pharmacists who employ or work with PAs point to professional, safe and ethical practice by PAs. Pharmacy owners and superintendent pharmacist, acknowledged experts under S.I. No. 488 of 2008, are satisfied that the PAs they employ to act in temporary absence of pharmacist have the knowledge, skills and fitness to act. When asked in the PAA survey, if the PA they employ or work with demonstrates the 25 competencies outlined in the PSI Core Competency Framework for pharmacists, the findings indicate over 90% of PAs were competent in 12 domains, over 80 % were competent in a further 10 domains and over 70% in 3 domains (see Appendix One for details).

Furthermore many went on to highlight how:

"*Our PA demonstrates all of the above very well she has seen many changes in Pharmacy and has adapted to them all, she exhibits and works towards the core competencies the same as any pharmacist in our business , she is a competent and capable member of staff who attends CPD and Webinars regularly she all ready works under a pharmacist and in line with the regulation which enables her to do day off cover , I can not see the reason for changing this. Her qualification will be taken from her and she will not be able to legally do the job she was employed to do , when all along she has been working and adhering to the regulations as required and keeping her CPD up to date*"

"The PA is far superior to a lot of pharmacists I have worked with in all areas of pharmacy and nothing can substitute the vast experience she has in the sector"

"Pharmaceutical Assistant I work with has more years experience and practical knowledge than any qualified pharmacists available to work locum or part time and I think credit should be given to them for years of work and emphasis placed on continuity of staff in a pharmacy rather than a task-based list"

"The level of interest and competence of my PA is on a par with my own and will in no way be replicated in a locus pharmacist doing a few days in my pharmacy. I am seriously considering selling my pharmacy than see it being compromised by anything less than the 100% commitment which I and my staff have provided our customers for 30+ years. A sad day for an independent pharmacy"

"a competent pharmaceutical assistant as I have in my employment, who works full time in my pharmacy is better placed to cover temporary absence than a locum pharmacist that has never worked in my pharmacy before"

"Pharmaceutical Assistants are a vital element of our Dispensing Pharmacy. Their experience and knowledge from many years in the dispensary is being undervalued and placed secondary to an elongated academic qualification. For accuracy, knowledge and professionalism I would place them on par with an MPharm graduate"

Effectiveness: It is a requirement of regulatory change that the measures should be properly targeted. Effectiveness also demands that regulations have to be enforced. The PSI has the necessary powers to inspect pharmacies to ensure that patient safety is not jeopardised. However, the PSI has not addressed enforcement, nor the additional cost of enforcement.

Proportionality: The PSI is required to demonstrate that the advantages of the new regime outweigh the disadvantages of the status quo. No such assessment has been completed. In particular, the PSI has not calculated the costs resulting from its proposed rule changes. These will involve redundancies, the closure of some rural pharmacies, and the reduction in opening hours as evident by PAA surveys. In addition, the PSI should have assessed a series of other options, including for example regulating PAs by way of amendments to the Pharmacy Act and/or a self-regulation by pharmacists.

Transparency: The PSI is required not only to discuss with stakeholders but to provide a considered response to submissions made by way of public consultation. None of the material points made by some 600 respondees in 2016 have been addressed. In fact, the April 2018 Report (on Temporary Absence) ignored submissions made on a draft Statutory Instrument published in 2016. The PSI has failed to publish documents essential to get a better appreciation of its position, in particular the risk assessment of PAs that it claims to have completed. Most worrying perhaps is that a minority of the six-person working group did not agree with the PSI's approach.

Consistency: All proposals for regulatory change should address anomalies and inconsistencies. The PSI is, on the one hand, effectively giving registered chemists the pretext to fire all the PAs employed (as they will no longer be able to dispense), while on the other hand the PSI is looking to the whole pharmacy profession to up its game and do more to meet patients' needs.

The only logic following this brief analysis is that the PSI should withdraw its proposal.

PSI Survey

Having regard to these over-arching comments, the PAA will be advising its members to respond to the PSI on-line survey in line with the enclosed briefing note (Appendix Two).

The PAA expects the PSI to respond to the serious criticisms set out in this submission - and in relation to the responses to the questions set out in the survey - before it submits the draft Statutory Instrument to the PSI Council.

Conclusion

The PAA is open to engaging with the PSI in a constructive manner, perhaps with the assistance of a third party facilitator, to reach a satisfactory resolution to the issues of temporary absence and the competency framework for PAs.

The PAA strongly recommends that the PSI consider the Association's minority report on temporary absence and better reflect the key issues set out in that report before the draft Statutory Instrument is referred to the PSI Council.[4]

PAA 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 as outlined In PSI Core Competency Framework.

August 2018

[4]Pharmaceutical Assistants Association (June 2018), *Shadow Report on the PSI Working Group on Temporary Absence Report (April 2018).*

Appendix One

Core Competencies demonstrated by PAs as judged by 99 respondents who act in role of pharmacy owner and/or superintendent pharmacists

Competency	Yes	Some what	No
1. Practice 'patient-centred' care e.g. ensures patient safety, empowers patient to manage their medication and health	93%	6%	1%
2. Practice professionally e.g. maintains patient confidentiality; obtains consent, treats with empathy, respect	95%	5%	
3. Practice legally e.g. understand and applies medicine, data protection, health and safety, consumer law	97%	3%	
4. Practice ethically e.g. makes and justifies decisions reflecting pharmacy and medicine laws	96%	3%	1%
5. Engages in appropriate continuing professional development e.g. understands and accepts importance of life-long learning	79%	16%	5%
6. Leadership skills e.g. contributes to developing and improving services for patients	73%	18%	9%
7. Decision-making skills e.g. gathers information from reliable sources to enable well founded decisions	88%	9%	3%
8. Team working skills e.g. collaborates and ensures effective handover to ensure continuity of patient care	92%	5%	3%
9. Communication skills e.g. communicates effectively with patients + carers using appropriate language, checking for understanding	94%	5%	1%
10. Manufactures and compounds medicines e.g. demonstrates the ability to perform pharmaceutical calculations accurately	85%	13%	2%
11. Manages the medicines supply chain e.g. stores medicines in a safe, organised, systematic and secure manner	96%	4%	
12. Reviews and dispenses medicines accurately e.g. applies knowledge to undertake a therapeutic review of the prescription to ensure pharmaceutical and clinical appropriateness of treatment	88%	12%	
13. Patient consultation skills e.g. Ensures medicines selection and advice reflects best evidence and guidance	92%	8%	
14. Patient counselling skills e.g. counsels patients providing appropriate information, ensuring understanding of optimal use.	92%	8%	
15. Reviews and manages patient medicines e.g. recognises and manages adverse drug reactions, inappropriate dosage	87%	12%	1%
16. Identifies and manages medication safety issues e.g. keeps abreast of emerging medication safety information	85%	10%	
17. Provides medicines information and education e.g. Provides accurate, quality and safe information and advice to patients, etc	90%	1%	
18. Public Health e.g. Identifies the primary healthcare needs of patients taking into account cultural and social setting of patient	80%	15%	5%
19. Health promotion e.g. provides information, advice and education on	80%	17%	3%

disease prevention and control and healthy lifestyle			
20. Research skills e.g. Possesses skills to investigate a medicine	76%	21%	3%
21. Self-management skills e.g. demonstrates organisation and efficiency in carrying out their work	91%	8%	1%
22. Workplace management skills e.g. works effectively with supervising/ superintendent pharmacist and documented procedures	91%	6%	3%
23. Human resources management skills e.g. engages with systems and procedures for performance management	76%	16%	6%
24. Financial management skills e.g. Demonstrates awareness of the health service reimbursement scheme	86%	12%	2%
25. Quality assurance e.g. understands the role of policies and procedures in the organizational structure	88%	10%	2%

.

Appendix Two

Suggested Replies to PSI Survey Questions

Introduction

PAs should indicate in their response to the first question that they have fundamental objections to the PSI's proposals and that the PSI should withdraw its proposals until all the issues set out in the PAA's (August 2018) submission are settled by way of a collaborative dialogue between the PAA and the PSI.

Question 4

Rule 4 (1)

Strongly disagree

- PA's qualifications allow them to dispense medicines and by extension they can cover temporary absences.
- No evidence to support a 'one hour' rule has been provided. The PSI should investigate the practice of temporary absence in other comparable jurisdictions before coming forward with a revised proposal.
- PAs have covered pharmacists' temporary absences over forty years and there is no evidence published by the PSI, HIQA, or HSE to demonstrate that their professional behavior in the supply of medicines, the safe and rational use of medicines has had adverse consequences for patients. On the contrary, pharmacists that employ and work with PAs attest their professional competency and experience as 'exemplary'. Hence if the rationale of Rule 4 (1) is genuinely to regulate to protect patient safety, limiting temporary absence to one hour per day, is misjudged and in all likelihood will create patient safety issues.
- In the majority of pharmacies outside large urban areas, PAs enable local pharmacies provide a six full day service, by covering in the temporary absence of the pharmacist.
- Requiring a pharmacist to work nine or more hours per day, six days a week poses significant risk to patient safety and also breaches the Working Time Directive Regulations.

- Rule 4 (1) therefore does not represent a proportionate response to patient safety as clinical evidence does not support the contention that PAs in dispensing medication pose a unique risk above that of a pharmacist to patient safety.
- It is arguable that an indirect consequence of the application of Rule 4 (1) would be that PAs would no longer be allowed to dispense medicines even if they worked under the supervision of a registered pharmacist who was not on temporary absence.
- Rule 4 (1) will restrict the rights of PAs to earn a living as their employability depends on being able to cover normal absences associated with a pharmacist (owner or employed) working in independent community pharmacies.

Question 5

If don't agree with proposed time, what do you believe should be the maximum time……

- Whenever the supervising pharmacist, who is required under the Pharmacy Act 2008 to be in whole time charge is absent, he/she is in temporarily absent. That is the time the PA should and is qualified to cover and would in normal circumstances cover lunch hour, days off, holidays, late nights, meetings.
- Defining temporary absence in terms of exact hours will make it an offence for a pharmacist to be absent for five minutes over the time set. In normal day to day live, things happen that cannot be foreseen, people have accidents, children become ill, traffic jams etc.
- If patient safety is at the heart of pharmacy regulation, ensuring all those handling medicines are competent to undertake their work safely should be the focus of any reforms. The solution therefore lies with bringing PAs under the PSI's core competency framework and making them subject to practice review and fitness to practice requirements.
- Pharmacists could be required to outline on registration how temporary absence will be operate on their premise, citing name of PA, CPD undertaken, SOP on hand over and support they will provide whilst temporary absent.

Question 6

Rule 4 (2) allow time to be taken as one single hour or 2 more period amounting to hour, etc.

Strongly disagree

- For the reasons listed above and in the PAA's submission.

Question 7

Rule 5 (1)

Agree

- This is already covered by Pharmacy Act 2007.
- Pharmacists employing PAs to cover their temporary absence are well placed to judge the competency of PAs (skills, experience and knowledge) ensuring patient safety and mitigating the need to define temporary absence to a set time.
- Pharmacists have worked with the PA providing cover so know their practice better than a locum pharmacist they may never work with.

Question 8

Rule 5 (2)

Neither agree or disagree

- It was not the intention of the 2007 legislation that PAs would manage a pharmacy. However, PAs are qualified to transact the business of the pharmacist in their temporary absence, including dispensing medicines, and indeed to carry out this task when they are present.

Question 9

Rule 6 (Duty Register)

Strongly disagree

- This question is ambiguous. Under the Pharmacy Act 2007, a duty register already requires a pharmacist and a PA to record hours. If this question implies that a separate register is established to just record when a PA is covering temporary absence i.e. every

time pharmacist leaves premise e.g. to buy sandwich, this is over bureaucratic and waste of time and resources.

- This is a disproportionate requirement.

Question 10

Rule 7 (make patients aware)

Strongly disagree

- Patients need assurance that the persons working in the pharmacy (those qualified to dispense advice and medicines) are qualified to perform these tasks. Distinguishing between superintendent pharmacist, supervising pharmacist, pharmacist, pharmaceutical assistant, locum pharmacist will create anxiety not provide assurance to patients. What will provide assurance is someone familiar to them who they know and trust to dispense their medication. What patients find must upsetting is having to deal with a locum, parachuted in for holiday cover etc. This is where the patient is most at risk.
- This proposal could be addressed if PSI registration certificates for all qualified staff were displayed in the pharmacy.

Question 11

Rule 8 (1) professional tasks

Strongly disagree

- PAs are qualified, experienced and skilled professionals, competent to dispense medicines. To ensure competency is maintained PAs should be covered by the PSI's CPD and core competency framework, which includes practice review.
- Defining the roles and responsibilities of PAs should be enshrined in primary legislation in the same manner as other persons working in a pharmacy.

Question 12

Rule 8 (2) consider risk when developing task list

Strongly disagree

- Such an approach it is not at all appropriate not least because the PSI failed to carry out a robust clinical risk assessment as part of the deliberative process in the formulation of these draft rules.
- The PSI should publish the evidence it has that PAs in dispensing medicines pose a material risk to patient safety. If no such evidence can be found the draft Statutory Instrument should be withdrawn.
- All health care professionals pose a potential risk to patients. In every other profession risk reduction is achieved through education (CPD) and competency framework (such as practice review). This is the only rational way to address risk and by extension patient safety.
- The PSI should engage with the PAA to explore how in practical terms PAs could be covered by CPD, a competency framework and fitness to practice rules.

Question 13

Rule 8 (3)

Strongly disagree

- The regulation of PAs, as with pharmacists generally, should be based on a risk-based approach that is proportionate and where the patient's safety is the key determinant.
- Only when there is robust evidence to hand will it be possible to re-cast the current roles and responsibilities of PAs.
- The PSI should review the professional tasks undertaken by PAs (with equivalent qualifications) in other jurisdictions before presenting final proposals.

Question 14

Rule 8 (4)

Neither agree nor disagree

Question 15

Not relevant until the PSI completes a benchmark review of the roles and responsibilities of PAs in other comparable jurisdictions.

Question 16

- Omitted cover for holidays, days off, and other short absences.

Question 17

The PSI should engage in a constructive manner with the PAA to address the issues raised in its August 2018 submission and in respondents' replies to the survey questions.

As a consequence, the draft Statutory Instrument should not be submitted to the PSI Council for consideration and approval until the outcome of these consultations is completed.

Whatever reforms are eventually agreed should be based on robust evidence, be proportionate, consistent, cost effective and above all agreed by consensus by the parties most affected.

PAs have a contribution to make to the delivery by the PSI of its strategy to meet patient needs.