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Professional practice following regulatory change: An evaluation using principles of "Better Regulation"

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Abstract

***Background*:** The provisions in place internationally to regulate the practice of healthcare professionals have undergone significant change. However, this changing regulatory environment as experienced by healthcare professionals in the practice setting has not to date been widely researched.

***Objective*:** To describe the "lived experience" of pharmacists in community practice in Ireland of the model of regulation introduced by the Pharmacy Act 2007: and their perception of it as fulfilling the seven principles of "better regulation": Necessity; Effectiveness/Targeted; Proportionality; Transparency; Accountability; Consistency and Agility.

Method: 20 community pharmacists purposively selected, shared their lived experiences of the Act, as implemented in a semi-structured interview. . A qualitative content analysis incorporating a framework analysis based on the seven principles of better regulation was used to analyze the data.

***Results*:** The Act and its implementation by the Pharmaceutical Society of Ireland (PSI) was not perceived overall by community pharmacists as fulfilling the principles of better regulation. While there was agreement that the Act was necessary, its implementation by the PSI was not viewed as being effective, targeted, proportional and consistent. The PSI was considered to act as a deterrence regulator that is not adequately transparent or accountable. The Act is not sufficiently agile to respond to changes in pharmacy practice.

Conclusion: Community pharmacists acknowledge the need for the Pharmacy Act but perceive that the PSI needs to adopt a more responsive approach to implementation if the Act is to be considered a model of better regulation. The study findings are of interest as there is little published research on how regulation is experienced by healthcare professionals who are subject to its provisions. The principles of better regulation provide an effective qualitative methodology to examine models of professional regulation based on the "lived experience" of regulatees.

Keywords: Healthcare professional, Community Pharmacist, Implementation, Lived Experience Pharmacy Law, Regulation.

Introduction

The regulation of healthcare professionals is characterized as formal social control introduced for the common good. As pharmacists increasingly play a vital role as members of multidisciplinary teams delivering patient care, the need to improve their regulation has been acknowledged in many advanced economies. The model of healthcare professional regulation in place in Ireland and its neighboring country, the United Kingdom (UK) remained relatively unchanged since the 19th century. However, in the last twenty years significant reform has been enacted in the UK, primarily in response to a series of medical scandals. In the case of medical regulation in the UK, this reform has been precipitated by market liberalization and public sector reform; changing public attitudes to expertise and risk and high profile medical scandals (Waring et al 2010). This change has been characterized by a shift away from a traditional model of pure self-regulation by professionals themselves to one of *"regulated (self-) regulation"* which is increasingly subject to external scrutiny and audit.[1] The emphasis on the public interest and patient safety is clearly shown in the processes and rules of Fitness to Practice for pharmacists in the UK and other Common Law jurisdictions.[2] In the United States (US), the recent change in regulatory focus from a prescriptive rules-based model of regulation to a "*standard of care"* one indicate a similar trend.[3]

The introduction of a new Pharmacy Act in Ireland in 2007 expanded the regulatory scope considerably, particularly in the area of discipline and continuing professional development (CPD).[4 (No.20 of 2007)] The Act extended the powers of the Pharmaceutical Society of Ireland (PSI), charged with implementing its provisions, to investigate and adjudicate upon complaints about pharmacists and pharmacies which if upheld may result in the cancellation of their registration. It also makes it a function of the PSI to ensure that pharmacists undertake CPD.

The Organisation for Economic Co-operation and Development (OECD) recommends that regulators should conduct periodic reviews of regulations following their implementation and that the legislature should monitor and periodically review that the system of regulation is working as intended.[5] Notwithstanding that the Pharmacy Act was ten years in place in 2017, no review of its implementation had been undertaken. This study addressed this deficiency and its aim was to examine how community pharmacists experienced the model of regulation introduced by the Pharmacy Act 2007 in their practice environment i.e. the "lived" experience.

The objectives of the study were:

- To describe how pharmacists in community pharmacy practice experience the model of regulation introduced by the Pharmacy Act 2007 and its implementation by the PSI;
- To describe how they perceive the Pharmacy Act 2007 and its associated secondary legislation as aligning with the seven principles of better regulation;
- To identify changes to the model of regulation and its implementation as appropriate.

The implementation of policy such as the introduction of regulation, has been described as "*what develops between the establishment of an apparent intention on the part of government to do something, or to stop doing something, and the ultimate impact in the world of action".*[6] It takes one of two approaches: top-down or bottom-up. The top-down approach is focused primarily on the effectiveness of policy by establishing the causal link between introduction and effect, with an emphasis on how the system delivers on the intentions of the policy or law makers at the top leading to its introduction. The bottom-up approach emerged in response to what was considered to be a significant shortcoming of the top-down approach, namely its singular focus on those central decision makers at the top[7,8,9]. Those engaged in implementing policy or law at

the frontline are identified as "*street level bureaucrats".*[7] Street level bureaucrats are essentially problem-solvers who in order to discharge their policy or regulatory function at the front-line need to be able to apply discretion to adapt it to local conditions.[10] Healthcare professionals like community pharmacists (CPs) having to comply with the provisions of regulation in the discharge of their professional services in the patient setting may be characterized as street level bureaucrats. This study which examined the lived experiences of CPs as street level bureaucrats with a changed model of regulation provides a methodology which can be used to examine the impact of regulation on the practice experiences of a range of healthcare professionals experience regulation .

Methodology

Principles of Better Regulation

Notwithstanding that the regulation of healthcare is widespread in both the UK and the US, there is little research available which examines or evaluates its impact.[11] This is attributed to the methodological challenges in completing such research.[11] Where regulation and its effects are considered, the trend is to quantify it in terms of numbers, weights and cost.[12] Framing the consideration of regulation in quantitative terms may "*over-technify*" the process making it difficult for those who are regulated to offer a counter argument in a similarly technical manner.[12] In a study examining housing regulation in Australia, it is noted that regulation is rarely examined from the perspective of those who are regulated and the case for using a qualitative approach to do so is presented.[13]

This qualitative study examining how CPs in Ireland experienced the changed regulatory model introduced by the Pharmacy Act 2007 derived its theoretical framework from both the theory of policy implementation and principles of regulation aligned with the model of responsive regulation (Ayers and Braithwaite 1992). . In 1995, the OECD published recommendations for improving regulation in its member states. [14] In the UK, these recommendations resulted in its Better Regulation Unit identifying five principles of effective regulation: transparent; accountable; targeted; consistent and proportionate.[15] In Ireland, the government introduced its White Paper "*Regulating Better*" on foot of these recommendations.[16] This paper identified six

principles for regulating better: necessity; effectiveness/targeted; proportionality; transparency; accountability and consistency. Since 2004, it has been the policy stance that any regulation introduced in Ireland is in accordance with these six principles. The unpublished study by Donoghue in 2009 examined the regulatory policy issues that impacted on public confidence in the disciplinary process in place at the time for nurses in Ireland. It researched the perceptions and attitudes of the relevant parties using the six principles of *Regulating Better.*

In the UK, the Professional Standards Authority (PSA), established to supervise the functioning and operation of nine regulatory bodies for various health and social care professionals, developed its own model of regulation "*Right Touch Regulation"* which identified six analogous principles for the effective regulation of healthcare professionals as follows: Proportionate; Consistent; Targeted; Transparent; Accountable and Agility. [17]

By consolidating the principles from both the *Regulating Better* and *Right Touch Regulation* policies, seven principles were identified which acted as the framework for the conduct of the study and its data analysis. They were collectively known as the principles of *"Better Regulation"* and are as follows:

Table 1. Study Principles of "Better Regulation"[16 (p.2), 17 (p.4)] Adapted by the authors

Necessity	Is the regulation necessary? Can it reduce red tape? Are the rules and structures that govern this area still valid?
Effectiveness/ Targeted	Is the regulation properly targeted? Is it going to be properly complied with and enforced?
Proportionality	Do the advantages of the regulation outweigh its disadvantages? Is there a smarter way of achieving the same goal?
Transparency	Are stakeholders consulted prior to regulating? Is the regulation clear and accessible to all? Is there good back-up explanatory material?
Accountability	Is the regulation clear as to precisely who is responsible to whom and for what? Is there an effective appeals process?

Consistency	Does the regulation give rise to anomalies and inconsistencies? Is best practice developed in one area applied when regulating other areas?
Agility	Is the regulation looking forward and capable of adapting to anticipate change?

Data collection Process

One-to-one semi-structured interviews were conducted to collect the data. A topic guide comprised of questions in three parts was designed to guide the conduct of the interviews. Part 1 comprised some relevant non-identifying details about the CP interviewee e.g. number of years practicing as a pharmacist and whether they were a pharmacy owner or employee; Part 2 provided for the experiences of CPs to be addressed according to broad regulatory provisions in the Act such as registration; education and training; experience and CPD; inspection/disciplinary activities and the PSI; Part 3 provided for CPs to recount their perceptions of the Act and its implementation according to the seven principles of better regulation.

Research ethical approval was sought and granted by the Human Research Ethics Committee-Humanities, of [Name of University] where the lead researcher was completing his research.

A pilot study comprising of two semi-structured interviews was conducted in advance to assure the appropriateness of the methodology and data collection process.

At the outset, a purposive heterogeneous sample of 38 community pharmacists (CPs) was identified from tutors on the National Pharmacy Internship Programme (NPIP) and invited to participate in the study. The NPIP incorporates a one year period of supervised practical training and must be successfully completed by all pharmacy graduates in order to be eligible to register and practice as a pharmacist in Ireland. The particular NPIP tutors were selected as they were all considered to have a good knowledge and understanding of the Act and its provisions. While this was the common link between them, CPs selected differed from one another in a range of ways including gender, status as a pharmacy owner or employee and number of years practicing (Holloway & Wheeler 2002).

154 23 CPs accepted the invitation to participate in the study while the remaining 15 did not respond.
155 2 CPs later withdrew citing work commitments and 1 CP was not further contactable. Over a
156 sixteen-week period from January to April 2017, semi-structured one-to-one interviews, with
157 reference to the study topic guide were conducted with the 20 CPs who agreed to participate
158 from the 38 originally invited (Table 2). . Interviewees were asked about their experiences and
159 perceptions of the Act in accordance with the study's topic guide described previously. Each
160 interview lasted an average of 64 minutes (range 41-85 minutes) and were recorded. Each
161 interview recording was subsequently transcribed by a professional transcriber and returned to
162 the researcher for review. Following this, it was forwarded to the interviewee for their review
163 and approval.
164 In a qualitative study, the sample size should be determined on the basis of informational needs
165 so that the research question can be answered with sufficient confidence (Krippendorff 2013,
166 Bengtsson 2016). While data saturation was achieved in advance of the completion of 20
167 interviews, interviews with all the CPs who agreed to participate in the study were undertaken
168 to assure the requisite confidence to the study's findings. .
169
170 **Table 2 Community Pharmacist (CP) Interviewees' Profile**

	Male (N=13)		Female (N=7)		Total
No. of years practicing (range)	Pharmacy Owner	Employee	Pharmacy Owner	Employee	
1-10	1	2	0	3	6
11-20	1	2	1	0	4
21-30	3	1	2	0	6
31-40	1	0	0	1	2
41-50	2	0	0	0	2
Total	8	5	3	4	20

171
172 *Data Analysis*
173 The interview data was analyzed using a qualitative content analysis which incorporated as its
174 first step a framework analysis. Once transcribed, the interview transcripts were transferred to
175 QSR NVivo® (Version 10) which supported the organization, management and analysis of the data.
176 A seven-stage procedure for a framework analysis was used to guide the analysis.[18] The stage of

this procedure to identify the analytical framework to use (Stage 4) was adapted to allow the seven principles of better regulation to be used to analyze and interpret the data. Following this, a comprehensive qualitative content analysis of the data was then undertaken to further analyze a number of themes that emerged from the framework analysis. A qualitative content analysis is normally represented as three main phases: preparing; organizing and reporting.[19] The preparing phase which involved becoming thoroughly familiar with the data had already been completed for the initial framework analysis. In the organizing phase, the data was categorised according to a process of open coding in which notes and as many headings as necessary were identified from the interview transcripts to describe all aspects of the content. [19] This was then followed by the creation of a number of categories which were then grouped into a limited number of higher order categories. The process of open coding and subsequent categorization of data was completed by the lead researcher and overseen by two other experienced qualitative researchers. No discrepancies of any significance in either the coding or categorization processes as completed by the lead researcher were identified by these researchers. The reporting phase presented the study's results as follows.

Results

Framework Analysis

Overall, the study found that apart from necessity, CPs did not perceive the Pharmacy Act as fulfilling any of the remaining principles of effectiveness/targeted, proportionality, transparency, accountability, consistency and agility. Table 3 details illustrative CP quotes aligned with each of the relevant principles.

Table 3 Principles of Better Regulation Framework Analysis Illustrative Quotes

Principle of Better Regulation	Illustrative Quotes
a. Necessity	*"…It actually gave a function and a proper role to the pharmacist really."* (a.1)
b. Effectiveness/Targeted	*"If you are an inspector …you need something to be able to report on and that is a piece of paper… I have three pharmacists on today*

	because I have a big patient load …but I am not measured on that". (b.1) *"it is a bit terrifying to see that people would have Fitness to Practise actions taken against them for a single error…….things seem to be a bit extreme."*(b.2)
c. Proportionality	*"I believe it is in proportion but more refinements are necessary…..*." (c.1) *"…in some ways we are treated guilty until proven innocent… There is all this weight of proof that we have to provide to show that we are not dangerous…"* (c.2) *"* [the] *only surprise was that* [there] *hadn't….*[been] *a pharmacist in front of* [Fitness to Practise] *who had been guilty of parking on a double-yellow line. Such was the trivial nature of what was coming before the* [Fitness to Practise] *committee"* (c.3) *"If you judge proportionality in terms of the size, number of staff and the PSI, it is way out of proportion".*(c.4)
d. Transparency	*"It is there, like a lawyer has written it in terms of the language…. you don't really know what is going on".* (d.1) *"Consultation process is a sham ….. it is a gimmick."* (d.2) *"There is no transparency. Trying to get information out of them is next to impossible".* (d.3)
e. Accountability	"*Quis custodiet ipsos custodes?"* [Who will guard the guards themselves?] (e.1) *"There is no way or mechanism of appealing…..".* (e.2) *"Well they are not accountable to the membership who pay all these fees".* (e.3)
f. Consistency	*"you have a pharmacist practicing in a plethora of other areas who aren't maybe subject to the same level of regulatory scrutiny".* (f.1)
g. Agility	*"Electronic transmissions of documents, faxing, we need to embrace more modern technologies. If there is an issue in the guidelines, the regulations, then it needs to be changed more quickly."* (g.1)

201

202 **1. Necessity**

All CPs were in agreement that the Pharmacy Act was necessary and that its introduction enhanced the professional role and function of pharmacists (a.1).

2. Effectiveness/Targeted

CPs were largely of the view that the Act's provisions addressing areas such as education, discipline and inspection of pharmacies were appropriately targeted.

However, the manner of the PSI's implementation of its regulatory provisions, particularly in relation to pharmacy inspections and the disciplinary process, was perceived as being neither effective nor targeted. CPs viewed the current inspection process to be ineffectively targeted on confirming compliance with a diverse check list of requirements, devoid of any meaningful assessment of the quality of care being provided in the pharmacy. (b.1)

The disciplinary process was not considered to be appropriately targeted with the PSI pursuing what were viewed as minor or single errors through the full disciplinary process. (b.2)

3. Proportionality

A minority of CPs interviewed considered that overall the Pharmacy Act and its implementation was proportional in terms of what was required to achieve its regulatory goal of protecting the public. (c.1)

However, the majority disagreed focusing on what they perceived as the PSI's disproportionate assessment of what risk the practice of community pharmacy posed to public welfare. (c.2)

CPs viewed the PSI's approach to invoking formal disciplinary procedures for what were considered minor infringements as disproportionate. (c.3)

Cost containment and minimization is an important aspect of proportional regulation and pharmacists referred to what they perceived as the PSI's high-cost base as being disproportionate to the numbers of pharmacists and pharmacies that they regulate. (c.4)

4. Transparency

Most CPs interviewed did not consider the implementation of the Act to be transparent. CPs referred to the legalistic language used in regulations and various related communications, stating they were difficult to understand. (d.1)

Stakeholder consultation is a feature of a transparent model of regulation. While CPs acknowledged that the PSI conducted stakeholder consultations before introducing new regulations, most were skeptical about the extent to which it took account of the views expressed in such consultations. (d.2)

The PSI was not considered to operate in a transparent manner and CPs perceived it as difficult to obtain information from. (d.3)

5. Accountability

While a minority of CPs perceived the PSI as being nominally accountable to the Minister for Health for the discharge of its statutory functions, most referred to the absence of any meaningful system of PSI accountability, citing the absence of any independent scrutiny of it or the model of pharmacy regulation. (e.1)

An important feature of an accountable model of regulation is the availability of an appeal process but a majority of CPs felt that there was no means available to them to appeal a decision of the PSI. (e.2)

CPs highlighted what they perceived as the lack of accountability by the PSI for its considerable financial resources. Notwithstanding that the PSI is almost exclusively funded by subscriptions from the profession, it was not considered accountable to it for the management of its finances. (e.3)

6. **Consistency**

A minority of CPs in the study were satisfied that there was a consistent approach to implementing the provisions of the Act. However, a majority indicated that the approach to implementation and enforcement was inconsistent noting that it was focused almost exclusively on community pharmacy practice. (f.1)

CPs also reported various inconsistencies in the implementation of the regulation with the community pharmacy sector which centered primarily on variations on facilities requirements within pharmacies.

7. **Agility**

The majority of pharmacists interviewed did not perceive the model of regulation provided by the Pharmacy Act and implemented by the PSI as being agile. They viewed it as rigid, unable to readily respond to the emerging changes in pharmacy practice such as societal and technological developments that have an impact on the delivery of pharmacy services. (g.1)

Qualitative Content Analysis

Following the framework analysis, a qualitative content analysis of the data was then conducted which further explored themes not directly related to the better regulation principles that emerged from the data. This resulted in a number of categories which were condensed into five higher order categories (Table 4).

Table 4 Higher Order and Related Categories identified by Qualitative Content Analysis

Higher Order Category	Related Categories	Illustrative Quotes
1. Relevance to Practice	a. Disconnect	*"it reflects absolute best practice, but I don't think it reflects practical practice… I don't think it supports best practice for patients."* (1a.1) *"….like I am not going to go into a solicitor's office and tell him how to do things. Or nursing, GP, I don't pretend to know because I don't know what working environment they are working in."* (1a.2)
	b. Administrative burden	*"the burden of administration etc……that inevitably takes us away from the patient."* (1b.1) *"I don't think the notion of cost to the pharmacist in implementing all this has crossed their mind."* (1b.2)

2. Disciplinary Provisions	c. PSI approach	*"It is extremely, extremely adversarial. It is quite unfair…"* (2c.1) *"somebody gave out Daktacort® and it should have been Daktarin Oral Gel®… That is an accident that anyone could do. To err is to be human and we all make mistakes…"* (2c.2) *"They feel they have to appear to the public to be robust, pro-active and doing the job they were sent in there to do and they must do so in a way that is visible."* (2c.3)
	d. Mediation	*"The first option is mediation. It has been used once in 10 years … The same remedial action can be achieved through mediation as that can be achieved through the adversarial, legalistic process and yet there is an aversion to using it."* (2d.1)
	e. Time delays & costs	*"I am tired of procedures taking years ….Having that weigh over people for periods, sometimes two and a half years."* (2e.1) *"Obviously we want a robust system of regulation but with it comes the associated costs…. I hear they are huge…….At what price does the regulation of a profession take to act in the public's interest?"* (2e.2)
3. Education	f. Integrated MPharm program	*"you don't want blocks of experience broken up into too short a period because…….from an employer's point of view, people can be sometimes less useful if they experience a short learning period and then are gone again."* (3f.1) *"people were floating figures of €7,000/€8,000….. People might not be able to afford to get into pharmacy because of the cost and is that fair?"* (3f.2)
	g. CPD	*I think a lot of the stuff that needs to get built into the* [Irish Institute of Pharmacy] *portfolio, I am not so sure that it is helpful* [to practice]*".* (3g.1) *"….Older pharmacists are afraid of CPD… the whole idea of OSCEs and digitally putting it onto it. ……from what*

		they have said …..'When I get CPD, I will take myself off the register'." (3g.2) *"I disagree with every single person on the register being called to do an OSCE every five years. ….There should be another layer there to identify pharmacies that are not up to scratch and then maybe using OSCEs as a way to get back on the register for people who have been censured or people who have been found not to have kept up with their CPD".* (3g.3)
4. Inspection/ Enforcement	h. Unannounced inspections	*"There was a stock take being done and they were very busy and* [the inspector] *walks in and says I am the inspector and I am going to inspect you. And during that inspection… a mistake was made……it was simply down to the pressure …."* (4h.1)
	i. Inspection Approach/ Inspectors	*"..the PSI's way of enforcing things are very black and white really… You often wonder do they understand what reality is about. I said pharmacy is a grey area. It is not black and white."* (4i.1) *"It is nothing to do with outcomes. It is nothing to do with how happy are my patients or are my patients getting a good service".* (4i.2) *"I think they would hand pick the inspectors so they would have the most vacant, blank look on their faces……. there is just no human element … It is down in black and white, and they are looking at a book … It is very hard to rationalize with them really*." (4i.3)
	j. Pharmacy Assessment System (PAS)	*"I am probably happier with the idea of self-assessment …..it comes from myself rather than ……them coming in and saying: 'No, no, you need to do this, that and the other.." (4j.1)* *"You do a section a month. ……You are going to be constantly reviewing your practice rather than constantly practicing….." (4j.2)*
	k. Engagement with the PSI	*"The PSI are very approachable. If you have an issue, generally they can give you help…… They have a distant*

5. Personal Experience of Regulation		*support role. They don't have a hands-on support role."* (5k.1) *"they are very inaccessible …. not very helpful if you have a query… very bureaucratic really."* (5k.2) "*I think there is a fear. I think the PSI and perception of the PSI among the profession at large is one of general fear….."* (5k.3)
	l. Acknowledge-ment of competence	"*we have qualified as a professional and* [should] *be given a certain amount of leeway and presumption that we will practice in a safe and legal way*." (5l.1) *"..in general, pharmacists would be very risk averse and we tend to be very compliant with regulation and legislation …"* (5l.2)
	m. Experience of older and younger pharmacists	*"…I can see why people over 50 choose to invariably decide that it is a young-man's game."* (5m.1) *"….it is causing a bit of a brain drain from community pharmacy. There is an awful lot of newly qualified people …..they really just don't want the nightmare associated with that and they are finding positions in industry, in regulation, in hospital far more attractive."* (5m.2)

1. Relevance to Practice

(i) Disconnect

CPs perceived a disconnect between them and the PSI as to the standard of practice necessary to protect the public interest. The PSI was perceived as requiring an absolute standard of best practice that was not commensurate with the practicalities of providing pharmacy services in the patient facing setting and which could militate against a pharmacist providing optimal patient care. (1a.1)

CPs considered that the lack of practical experience of providing pharmacy services in a patient facing environment among certain members of the PSI's Council and its permanent staff may be a contributory factor in this regard. (1a.2)

(ii) Administrative Burden

The increased administration or *"red tape"* for CPs associated with the Act further contributed to the sense of the PSI's disconnect from practice. It was perceived that the PSI does not appreciate the effect its administrative requirements have on diverting CPs away from providing patient care. (1b.1)

CPs were also of the view that the PSI did not give any consideration to the financial and other costs that its administrative requirements impose on CPs and pharmacies. (1b.2)

2. Disciplinary Procedures

(i) PSI Approach

CPs viewed the PSI's approach to discipline as being adversarial and heavy-handed. (2c.1)

CPs considered that the PSI disproportionately tends to pursue incidences of less serious dispensing errors through the disciplinary route, notwithstanding that errors are an unavoidable aspect of professional practice. (2c.2)

CPs consider this pursuit of disciplinary action by the PSI to be based on a belief by regulators that they have to be seen to be taking action in pursuit of the public interest. (2c.3)

(ii) Mediation

The Act includes provision for complaints to be resolved by mediation but CPs perceive that it is rarely pursued. (2d.1)

(iii) Time Delays and Costs

CPs were concerned by the protracted time that it takes for cases to be determined and the high costs associated with the disciplinary process. (2e.1, 2e.2)

3. Education

(i) Integrated MPharm program

Since 2014, the PSI only accredits five year degree programs which incorporate the periods of practical training during Years 4 (four months) and 5 (eight months).

CPs expressed varying concerns about the revised program and its structure. These centered on whether the two separate periods of practical training adequately prepares graduates for practice when compared to the single twelve-month period of practical training previously in place and the resulting lack of continuity for training establishments that no longer have students completing continuous and successive twelve month internships. (3f.1)

CPs were also concerned about the additional financial pressures the revised program format imposed on students. In addition to students no longer receiving payment during their periods of practical training, the fee to complete the fifth year of the program will be substantially higher than that previously in place. These changes may militate against students from less economically advantaged backgrounds choosing to study pharmacy. (3f.2)

(ii) CPD

All CPs in the sample were supportive of the introduction of mandatory CPD for all pharmacists. However, many found the reflective model of CPD introduced to be onerous and of limited relevance to their practice. (3g.1)

Engaging with the CPD requirements is exclusively by online means. A number of CPs felt that this disadvantaged older pharmacists whose IT skills may be limited and may precipitate them retiring prematurely from practice. (3g.2)

A further CPD requirement that all practicing pharmacists in a "*patient facing*" role would periodically have to undergo a practice review in the form of an Objective Structured Clinical Examination (OSCE) was considered. While some CPs agreed that everyone should periodically undergo such a review, others did not stating that such reviews should be more effectively targeted at those pharmacists who are experiencing difficulties in their practice. (3g.3)

4. Inspection/Enforcement

(i) Unannounced Inspections

All of the CPs interviewed acknowledged the need for the PSI to inspect pharmacies. However, most of them raised concerns about how the PSI's policy of conducting routine inspections on an "*unannounced"* basis i.e. without any prior notification to the pharmacy concerned. CPs felt that

this created unnecessary disruption in the pharmacy and had the potential to undermine patient safety. (4h.1)

(ii) Inspection Approach/Inspectors

CPs considered the PSI's approach to inspection to be one of law enforcement rather than a means to support and motivate CPs to enhance their practice. It was perceived as enforcing the law in a rigid and uncompromising manner that failed to take account of the complexities of the delivery of a personalized healthcare service. (4i.1)

CPs reported that inspectors during inspections focused on identifying shortcomings in the pharmacy according to a detailed check list of requirements which very often did not represent an accurate overall assessment of the quality of the pharmacy service being delivered. (4i.2)

The experience of CPs with individual PSI inspectors varied with some reporting that they found them to be largely agreeable whereas others reported a less favorable engagement. (4i.3)

(iii) Pharmacy Assessment System (PAS)

CPs largely welcomed the introduction of the PAS, a self-audit tool for them to use in their pharmacies as something that would assist them in improving their practice. (4j.1)

However, CPs felt the requirement for it to be conducted biannually was unnecessary and added to their already significant regulatory administrative burden. (4j.2)

5. Personal Experience of Regulation

(i) Engagement with PSI

A number of CPs reported their engagement with the PSI to be largely positive albeit with some qualification. (5k.1)

For others, their experience was generally unfavorable, finding the PSI slow to respond to queries and generally unhelpful. (5k.2)

All CPs referred to the fear and unease that the PSI creates within the profession. (5k.3)

(ii) Acknowledgement of Competence

In addition to creating fear, many CPs considered that the PSI does not appear to acknowledge their professional competence or trust them to act in the best interests of their patients. This results in pharmacists feeling that they must constantly demonstrate their professional competency to the PSI. (5l.1)

A number of CPs perceived that this lack of trust was unwarranted and that CPs were largely compliant with the various regulatory requirements. (5l.2)

(iii) Experience of Older and Younger CPs

A number of CPs referred to what they perceived as the effect of the model of pharmacy regulation on the longevity of both older and younger pharmacists in community practice. In addition to the CPD requirements, the demands of being a supervising pharmacist are perceived as precipitating the premature exodus of older pharmacists from community pharmacy practice. (5m.1)

CPs commented that the Act and its implementation by the PSI was acting as a disincentive to younger pharmacists choosing to pursue their career in community practice, and making roles in other sectors of the profession where the regulatory burden is considered not to be as great more attractive. (5m.2)

Discussion

The study found, based on the lived experiences of CPs that while they agreed that the Pharmacy Act was necessary, they did not consider that the Act or its implementation by the PSI fulfilled any of the remaining principles of better regulation. In its Corporate Strategy 2018-2020, the PSI identified its central organizational goal as assuring public trust in pharmacy through effective regulation.[20] It seeks to achieve this by regulating in ways that are proportionate, effective and risk-based. However, CPs perceived the Act and its implementation by the PSI as imposing a uniform *"one-size fits all"* standard of practice that fails to acknowledge the constraints present

when delivering front-line pharmacy services. The PSI's approach to regulation was considered to be poorly targeted and disproportionate, characterized by an absence of trust in their professional competence to practice safely and effectively and where they were viewed as *"guilty until proven innocent".* The UK's PSA has acknowledged the importance of building and maintaining trust between professionals and regulators.[21]

The approach of regulators has been differentiated into those who view regulatees as complying only when confronted with punitive sanctions (deterrence regulators) and those who believe in the role of persuasion to encourage compliance with regulatory requirements (compliance regulators).[22,11] The experiences of CPs with the PSI's inspection and disciplinary processes reflect those of a deterrence regulator and influenced their assessment of the Act as not being effective/targeted and proportional. While the need for an inspection system was unequivocally acknowledged by CPs, many viewed it as enforcing a series of rigid *"black and white"* requirements that fail to acknowledge the need for CPs to apply discretion to act in the best interests of their patients. The PSI's policy of only conducting unannounced inspections was viewed as disproportionate and mistrusting ofCPs. CPs were similarly unequivocal in their support for a disciplinary system but were concerned that the PSI adopted a *"heavy-handed"* adversarial approach to it, invoking disciplinary action for relatively minor transgressions: disproportionately prosecuting the more serious charge of professional misconduct and appearing to eschew using mediation to resolve complaints. Concerns were raised about the delay in cases being heard and the adverse toll, both professionally and personally that delays in the conduct of the disciplinary process have on those involved. In the UK, it has been shown that for doctors who were the subject of General Medical Council disciplinary procedures, one of the most stressful aspects of the process reported was its prolonged duration.[23]

Regulators should be responsive to the conduct of those they regulate when determining what regulatory action, if any, is required.[24]The model of responsive regulation eschews the application of pre-defined and immutable sanctions in favor of a response that takes account of the particular circumstances presenting, resulting in a hierarchy of regulatory responses. Responsive regulation in the context of regulating healthcare has been described as: *"regulators*

are more likely to succeed by using mechanisms that are responsive to the context, conduct and culture of those being regulated. Escalating sanctions can be invoked".[25] It advocates regulators adopting the approach of a compliance regulator, viewing those they regulate as sharing common objectives and purpose, in return for increasingly trusting them to act in the best interests of their patients.[11] The PSA also acknowledges that the adversarial approach adopted by many regulators when adjudicating upon complaints is not optimal and in its proposals for reform of healthcare professional regulation in the UK, advocates a model of regulation that aims *"to minimize the adversarial and legalistic aspects that are prevalent in the current models".*[26] The Department of Health in the UK is currently reviewing the model of regulation of healthcare professionals, noting that it must become more responsive so that it can protect patients and support professionals to learn from their experiences and mistakes while also becoming less adversarial and costly, faster and simpler.[27] The PSI acknowledges the significance of the disciplinary process in protecting public welfare but makes minimal reference in its most recent corporate strategy to the need to reform it and does not address any concerns regarding the adversarial nature of its conduct. [20]

This is a disconnect between the PSI and CPs as to the regulatory action required to protect the public interest, explained in part by a perceived disparity in the relative assessment of the risk posed by the provision of pharmacy services. One of the pre-requisites for risk-based regulation has been identified as the need for regulators to be able to reliably assess the probability and consequences of adverse outcomes occurring that are potentially unacceptable, and having a range of enforcement tools in place to deploy in response to increasing risk.[28] The model used by the PSI to assess risk in community pharmacies is not publicly available but CPs perceive it as not being appropriately targeted or able to effectively assess the relative risk accruing to public health on a case by case basis. This results in the PSI being perceived as demanding higher standards of service delivery and infrastructure than what is considered necessary or proportionate by CPs to safely and effectively deliver services to the patient.

The Pharmacy Act 2007 includes a number of provisions pertaining to education including the introduction of mandatory CPD. One CPD related requirement introduced by the PSI is that all those in *"patient-facing"* practice as defined under the relevant Rules undergo periodic practice

reviews. This requirement was largely informed by the model originally used by the Ontario College of Pharmacists (OCP) in Canada.[29] The original form of the practice review introduced by the OCP was a knowledge assessment and an OSCE in a simulated setting. This has recently changed and the OSCE has been replaced by a practice assessment conducted in the pharmacist's place of practice.[30] Some CPs considered that a more targeted approach to this *de facto* requirement for professional revalidation should be adopted by the PSI, whereby only those patient-facing pharmacists whose practice gave rise to concern would be eligible for a practice review. This would represent a more focused risk based approach to the selection process and would align with the recommendation that revalidation requirements should be limited to what is necessary to minimize the risk of healthcare practice without placing unnecessary burdens on practitioners or others involved in the process.[31]

The stated values of the PSI *inter alia* are of everyone counting and working together: *"we value, appreciate and respect everyone that we engage with"* and *"we work in partnership with our colleagues and all our stakeholders"*. [20] However, rather than feeling valued, appreciated or respected, most CPs reported experiencing fear and stress when engaging with the PSI. CPs didn't perceive the PSI as working as a compliance regulator in partnership with them. Many felt that the PSI lacked a practical understanding and appreciation of the complexities of delivering frontline pharmacy services which may in part be due to the PSI's Council having a non-pharmacy registrant majority. When compared to regulatory systems in Northern Ireland, Great Britain, Australia, New Zealand and various Canadian provinces, the PSI is alone in having a non-pharmacy registrant majority on its governing body.

The OECD states that an objective of good regulator governance is to enhance public and stakeholder confidence in its decisions and actions.[5] It recommends that regulators should undertake regular and purposeful engagement with those it regulates and other stakeholders, focused on improving the operation and outcomes of the regulatory framework. The PSI has committed to "*reviewing how we can make the system of regulation as understandable, simple and transparent as possible so that compliance is facilitated*".[20] However, CPs perceived it as closed and difficult to engage with, while both the regulations and supporting practice material provided by it were viewed as being inaccessible and legalistic in their presentation. Most CPs

perceived the regulatory consultation process that the PSI undertakes with stakeholders as being largely perfunctory with the PSI not giving any meaningful consideration to their views. For CPs, this supported their perception that the PSI does not acknowledge their competence or value their commitment to protecting the public interest.

The OECD's best practice principles for regulators recommends that regulators should be accountable to government or legislative oversight bodies and that regulatees should readily have access to an appeals process[5]. In the UK, the PSA acts as an oversight body for nine regulators for various health and social care professionals in the UK.[32] It has been described as a "*meta regulator*", the *de facto* regulator of the regulators but the PSA views itself, not as a regulator but an oversight and audit body with the aim of improving professional regulation.[33] For many CPs in this study, the PSI is perceived as largely unaccountable leading one interviewee to ask *"Quis custodiet ipsos custodiens?"* There is no effective appeals process available to CPs should they wish to contest any finding of the PSI in any matter other than a referral to the High Court in the case of a decision to impose a disciplinary sanction other than censure or admonishment. In relation to the PSI's own governance, CPs perceive that its Council does not adequately hold the permanent executive to account for its implementation of the Act. The PSIhas referred to it being held to account by its stakeholders and the public.[20] However, while it has committed to engaging independent assessors to provide objective evidence that it is operating to high standards of performance and delivering value-for-money, it does not specifically address its own accountability *per se.*

The regulatory provisions contained within the Pharmacy Act 2007 addressing pharmacy practice relate almost exclusively to community pharmacy practice which CPs consider a regulatory inconsistency. When the Pharmacy Bill, leading to the introduction of the Act was introduced in parliament, the Minister of Health noted that a second Pharmacy Bill would follow at a later date to address *inter alia* the regulation of hospital pharmacy practice. Twelve years on, this second bill remains outstanding and the PSI's regulatory remit remains almost exclusively focused on community pharmacy practice.

The PSA developed the principle of agility for inclusion in its *Right Touch Regulation Revised* policy.[17] Agile regulation is concerned with being able to look forward to the future and being able to anticipate change and adapt accordingly. The PSI acknowledges the importance of it being adaptable, stating that its *"regulatory approaches must not stand in the way of innovation and developments"* and be *"capable of responding to unanticipated developments"*.[20] However, most CPs in the study did not consider the Act or its implementation to represent agile regulation. While a number of CPs acknowledged some advances in their scope of practice since its introduction, the consensus view among CPs was that the Act was not sufficiently agile to respond to developments in pharmacy practice and that the PSI appears unwilling to facilitate such developments notwithstanding its duty under the Act to *"take suitable action to improve the profession of pharmacy"*.[4 (Section7)] In some instances, this resulted in patient care being compromised or worthwhile opportunities to enhance the model of care being thwarted. Some CPs noted that the PSI needed to be more agile and adaptable in its approach to regulatory enforcement if the recommendations set out in its "*Future Pharmacy Practice in Ireland-Meeting Patients' Needs Report"* are to be met.[34]

Conclusion

Notwithstanding the extent to which the delivery of healthcare services is regulated internationally, there is a relative absence of studies on the impact or effects of that regulation. This has been attributed to the methodological challenges posed by such research. The regulation of healthcare professionals such as pharmacists, medical practitioners and others is an important aspect of protecting the public interest but these regulatory systems are rarely reviewed to assess whether they are achieving their regulatory objectives or to examine the effect on those regulated. This study provides an effective qualitative methodology using the principles of better regulation and the lived experiences of CPs to examine the system to regulate pharmacy in Ireland. The methodology can be utilized to undertake studies of regulatory systems in place for other healthcare professionals, not only in Ireland but internationally. The study finds that while the Pharmacy Act is perceived as being necessary by CPs, it is not considered as fulfilling any of the remaining principles of better regulation. The PSI is largely perceived as a deterrence regulator that fails to adopt a responsive approach to the implementation and enforcement of

the Act's provisions, based on what is considered an inappropriate assessment of the risk posed to public health and safety by the provision of pharmacy services by CPs.

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Conflicts of Interest

None

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