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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.

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

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

41

## 42           **Introduction**

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

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

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

72 The objectives of the study were:

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

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

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

## 96 **Methodology**

### 97 *Principles of Better Regulation*

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

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

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

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

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

130 **Table 1. Study Principles of "Better Regulation"**<sup>16 (p.2), 17 (p.4)</sup> Adapted by the authors

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

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

131

132 *Data collection Process*

133 One-to-one semi-structured interviews were conducted to collect the data. A topic guide  
134 comprised of questions in three parts was designed to guide the conduct of the interviews. Part  
135 1 comprised some relevant non-identifying details about the CP interviewee e.g. number of years  
136 practicing as a pharmacist and whether they were a pharmacy owner or employee; Part 2  
137 provided for the experiences of CPs to be addressed according to broad regulatory provisions in  
138 the Act such as registration; education and training; experience and CPD; inspection/disciplinary  
139 activities and the PSI; Part 3 provided for CPs to recount their perceptions of the Act and its  
140 implementation according to the seven principles of better regulation.

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

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

145 At the outset, a purposive heterogeneous sample of 38 community pharmacists (CPs) was  
146 identified from tutors on the National Pharmacy Internship Programme (NPIP) and invited to  
147 participate in the study. The NPIP incorporates a one year period of supervised practical training  
148 and must be successfully completed by all pharmacy graduates in order to be eligible to register  
149 and practice as a pharmacist in Ireland. The particular NPIP tutors were selected as they were all  
150 considered to have a good knowledge and understanding of the Act and its provisions. While this  
151 was the common link between them, CPs selected differed from one another in a range of ways  
152 including gender, status as a pharmacy owner or employee and number of years practicing  
153 (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**

No. of years practicing (range)	Male (N=13)		Female (N=7)		Total
	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
<b>Total</b>	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.<sup>18</sup> The stage of

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

192

## 193 **Results**

### 194 ***Framework Analysis***

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

199

200 **Table 3 Principles of Better Regulation Framework Analysis Illustrative Quotes**

Principle of Better Regulation	Illustrative Quotes
<b>a. Necessity</b>	<i>"...It actually gave a function and a proper role to the pharmacist really." (a.1)</i>
<b>b. Effectiveness/Targeted</b>	<i>"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</i>

	<p><i>because I have a big patient load ...but I am not measured on that".</i></p> <p>(b.1)</p> <p><i>"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."</i>(b.2)</p>
<b>c. Proportionality</b>	<p><i>"I believe it is in proportion but more refinements are necessary....."</i></p> <p>(c.1)</p> <p><i>"...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..."</i> (c.2)</p> <p><i>" [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"</i> (c.3)</p> <p><i>"If you judge proportionality in terms of the size, number of staff and the PSI, it is way out of proportion".</i>(c.4)</p>
<b>d. Transparency</b>	<p><i>"It is there, like a lawyer has written it in terms of the language.... you don't really know what is going on".</i> (d.1)</p> <p><i>"Consultation process is a sham ..... it is a gimmick."</i> (d.2)</p> <p><i>"There is no transparency. Trying to get information out of them is next to impossible".</i> (d.3)</p>
<b>e. Accountability</b>	<p><i>"Quis custodiet ipsos custodes?" [Who will guard the guards themselves?]</i> (e.1)</p> <p><i>"There is no way or mechanism of appealing.....".</i> (e.2)</p> <p><i>"Well they are not accountable to the membership who pay all these fees".</i> (e.3)</p>
<b>f. Consistency</b>	<p><i>"you have a pharmacist practicing in a plethora of other areas who aren't maybe subject to the same level of regulatory scrutiny".</i> (f.1)</p>
<b>g. Agility</b>	<p><i>"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."</i> (g.1)</p>

201

202 **1. Necessity**

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

## 205 **2. Effectiveness/Targeted**

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

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

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

## 215 **3. Proportionality**

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

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

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

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

## 226 **4. Transparency**

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

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

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

## 236 **5. Accountability**

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

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

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

## 248 **6. Consistency**

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

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

256

257 **7. Agility**

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

262 **Qualitative Content Analysis**

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

267 **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	<i>"it reflects absolute best practice, but I don't think it reflects practical practice... I don't think it supports best practice for patients."</i> (1a.1)  <i>"...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."</i> (1a.2)
	b. Administrative burden	<i>"the burden of administration etc.....that inevitably takes us away from the patient."</i> (1b.1)  <i>"I don't think the notion of cost to the pharmacist in implementing all this has crossed their mind."</i> (1b.2)

<b>2. Disciplinary Provisions</b>	c. PSI approach	<p><i>"It is extremely, extremely adversarial. It is quite unfair..." (2c.1)</i></p> <p><i>"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)</i></p> <p><i>"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)</i></p>
	d. Mediation	<p><i>"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)</i></p>
	e. Time delays & costs	<p><i>"I am tired of procedures taking years ....Having that weigh over people for periods, sometimes two and a half years." (2e.1)</i></p> <p><i>"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)</i></p>
<b>3. Education</b>	f. Integrated MPharm program	<p><i>"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)</i></p> <p><i>"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)</i></p>
	g. CPD	<p><i>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)</i></p> <p><i>"...Older pharmacists are afraid of CPD... the whole idea of OSCEs and digitally putting it onto it. ....from what</i></p>

		<p><i>they have said ..... 'When I get CPD, I will take myself off the register'." (3g.2)</i></p> <p><i>"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)</i></p>
<b>4. Inspection/ Enforcement</b>	h. Unannounced inspections	<p><i>"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></p>
	i. Inspection Approach/ Inspectors	<p><i>"..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)</i></p> <p><i>"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></p> <p><i>"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)</i></p>
	j. Pharmacy Assessment System (PAS)	<p><i>"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)</i></p> <p><i>"You do a section a month. ....You are going to be constantly reviewing your practice rather than constantly practicing....." (4j.2)</i></p>
	k. Engagement with the PSI	<p><i>"The PSI are very approachable. If you have an issue, generally they can give you help..... They have a distant</i></p>

<p><b>5. Personal Experience of Regulation</b></p>		<p><i>support role. They don't have a hands-on support role.”</i> (5k.1) <i>“they are very inaccessible .... not very helpful if you have a query... very bureaucratic really.”</i> (5k.2) <i>“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.....”</i> (5k.3)</p>
	<p>I. Acknowledgement of competence</p>	<p><i>“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.”</i> (5l.1) <i>“..in general, pharmacists would be very risk averse and we tend to be very compliant with regulation and legislation ...”</i> (5l.2)</p>
	<p>m. Experience of older and younger pharmacists</p>	<p><i>“...I can see why people over 50 choose to invariably decide that it is a young-man’s game.”</i> (5m.1) <i>“...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.”</i> (5m.2)</p>

268

269 **1. Relevance to Practice**

270 **(i) Disconnect**

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

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

279           **(ii)     Administrative Burden**

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

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

286    **2.   Disciplinary Procedures**

287           **(i)     PSI Approach**

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

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

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

294           **(ii)    Mediation**

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

297           **(iii)   Time Delays and Costs**

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

300    **3.   Education**

301           **(i)     Integrated MPharm program**

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

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

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

#### 314 (ii) CPD

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

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

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

### 326 4. Inspection/Enforcement

#### 327 (i) Unannounced Inspections

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

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

333 **(ii) Inspection Approach/Inspectors**

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

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

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

343 **(iii) Pharmacy Assessment System (PAS)**

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

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

348

349 **5. Personal Experience of Regulation**

350 **(i) Engagement with PSI**

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

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

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

356           **(ii) Acknowledgement of Competence**

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

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

363           **(iii) Experience of Older and Younger CPs**

364 A number of CPs referred to what they perceived as the effect of the model of pharmacy  
365 regulation on the longevity of both older and younger pharmacists in community practice. In  
366 addition to the CPD requirements, the demands of being a supervising pharmacist are perceived  
367 as precipitating the premature exodus of older pharmacists from community pharmacy practice.  
368 (5m.1)

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

373

374           **Discussion**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 510 **Conclusion**

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

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

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528 **Conflicts of Interest**

529 None

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