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WEB PAPER

New fitness-to-practice requirements for pharmacists in Ireland: Implications for undergraduate pharmacy education

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Abstract

Internationally, there is tighter monitoring and enforcement of fitness-to-practice requirements in healthcare, which are being specified within legislation and guidelines. In Ireland, the Pharmacy Act 2007, that was recently published and is being gradually implemented, includes a provision for monitoring fitness-to-practice of pharmacists practicing here. This will mean that upon initial and continued registration by the Council of the Pharmaceutical Society of Ireland, pharmacists must satisfy a fitness-to-practice committee. Two routes by which a pharmacist can be deemed unfit to practice are specified within the Act – on the basis of ill health and through technical incompetence/malice. However, the exact nature of professional, cultural, and technical competencies required to satisfy these new fitness-to-practice requirements remain undecided and a further consultation with all stakeholders is required. Importantly, this consultative process must consider current practice standards and raise awareness of these issues among pharmacists while also considering the current and future undergraduate pharmacy students, i.e. the future pharmacists of Ireland. Radical cultural shifts in monitoring fitness-to-practice, with full professional accountability, must inform changes in the undergraduate curriculum and in assessing students, such that when they graduate, they are thoroughly prepared for ongoing fitness-to-practice scrutiny. Here, different approaches to international pharmacy education that may help pharmacy educators in Ireland prepare their students for the new fitness-to-practice requirements are reviewed and discussed.

Introduction

International trends in regulating fitness-to-practice among healthcare professionals

The concept of professionals being fit to practice is not restricted to health professionals, but rather includes all jobs in which professionals are entrusted with client funds, sensitive information, or particular responsibility for other people's well-being or where specialist technical abilities are required. However, healthcare professionals, including pharmacists, occupy a particularly privileged position in the professional realm, not least because their competence can influence patients' morbidity and mortality. Aside from criminal matters, there are various other behaviors, competency issues, and attitudes that can render a healthcare professional unfit to practice. These may include, but are not restricted to, mental illness, racist, or sadist attitudes, bankruptcy, abuse of drugs or alcohol, inappropriate sexual behavior, malice, and technical incompetence (Rubin 2002; Rudd & Stack 2006; Whiting 2007).

International trends in regulating fitness-to-practice among healthcare professionals

Within healthcare professions, the overall trend in developed countries is one in which fitness-to-practice is being more stringently monitored and enforced. There is a palpable shift

Practice points

- There are three pharmacy schools in the Republic of Ireland. They each deliver a 4-year BSc degree in pharmacy, together training ~170 new pharmacists each year.
- The fifth year of pre-registration training for pharmacists is currently arranged under the auspices of the PSI and outside of the university setting. It is not funded by the government except for those graduates who opt to complete this training in a public hospital.
- Fitness for registration and fitness-to-practice requirements for pharmacists practicing in Ireland have been introduced recently by the Irish Government via the Pharmacy Act 2007, but have not yet been fully implemented.
- International comparisons suggest that in addressing the new fitness-to-practice requirements, both the traditional undergraduate degrees and the existing pre-registration training model in Ireland could be improved by assessing professional competencies and by implementing a more structured system.

in emphasis, enshrined within legislation and guidelines, aimed at detecting those who are unfit to practice before they do damage rather than learning from those who inflict

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serious damage (Academic Pharmacy Group 2005; Baker 2006; Irvine 2006; Noyce 2006). Within the British Isles, examples of the latter include the cases of Michael Neary, Harold Shipman, and the Bristol Paediatric Cardiac Surgery Unit. While each of these cases of medical incompetence prompted inquiries and sanctions by the relevant medical councils, they clearly did so too late to save the lives or quality of lives of those victims of medical practitioners who were unfit to practice within their chosen specialty. This shift in focus toward ensuring professional competence, rather than recognizing incompetence at a later stage should be welcomed. Furthermore, since professional competency training begins at undergraduate level, the implications of fitness-to-practice, requirements for undergraduate curricula and for students' behaviors and attitudes are receiving much attention in the educational literature (Rubin 2002; Academic Pharmacy Group 2005; Whiting 2007; Goldie 2008; Petit & Foriers 2008).

Registration of pharmacists in Ireland

In Ireland, pharmacists are eligible for registration on the statutory register held by the Irish regulatory body for pharmacy – the Pharmaceutical Society of Ireland (PSI) – upon completion of a pharmacy degree and further pre-registration training in the workplace. There are three pharmacy schools in the Republic of Ireland (Trinity College Dublin; TCD, University College Cork, and the Royal College of Surgeons in Ireland; RCSI). Each of them offers a similar, 4-year, full-time Bachelor of Science in Pharmacy degree that is accredited by the PSI, which has the power to approve and accredit the degree content. It is fair to say that each of these degrees is structured in a traditional academic way with students learning general, science-based principles of pharmacy in the first 2–3 years of the degrees and practical/clinical pharmacy skills being largely taught in the latter stages of the degrees. Traditional disciplines of relevance to pharmacy, including pharmaceutical chemistry, pharmaceuticals, pharmacology, pharmacognosy, pharmaceutical analysis, biology, biochemistry, microbiology, mathematics/statistics, and physiology are all covered, as either stand-alone subjects or within integrated modules. Notwithstanding this approach, students are taught Practice of Pharmacy throughout the entire degree and each of these schools are embracing novel teaching methods to some extent.

Irish pharmacy graduates currently undertake a further 1-year pre-registration training, following which they sit for a licensing examination, run by the PSI, that qualifies them for full PSI registration. The PSI does not currently maintain a register of pharmacy undergraduate students, although provision for a roll of students is included in the Pharmacy Act 2007 (Section 24.1). Under the European Union Recognition of Professional Qualifications Directive (Article 44; Annex V), the PSI is obliged to recognize qualifications obtained by trained pharmacists in any of the EU member states. Thus, EU-trained pharmacists in good standing who have qualified in any of the EU member states and who possess appropriate linguistic skills are also entitled to apply for PSI registration (European Parliament and Council of the European Union 2005). Pharmacists holding qualifications

from other countries are considered on a case-by-case basis for registration within the context of legislation dictating the recognition of qualifications.

Fitness-to-practice requirements for pharmacists in Ireland and the Pharmacy Act 2007

While entry to the register of pharmacists held by the PSI has been well regulated since the inception of that society and its predecessor, the powers of the PSI in relation to ongoing registration of pharmacists were very limited prior to the current Pharmacy Act 2007, which is being implemented gradually (Government of Ireland 2007). This Act replaced legislation dating from 1875 and the 1791 Apothecaries' Hall Act, thereby providing a 'root and branch' overhaul of the sector. Previously, the PSI had no means of sanctioning pharmacists or striking off incompetent practitioners. There was also no requirement for a registered pharmacist to be actively engaged in pharmacy or to participate in continuing professional education (CPE) or continuing professional development (CPD). Rather, these were considered matters of personal–professional responsibility. The new Pharmacy Act has attempted to address at least some of these important issues. Part 5 of the Act specifies a range of offenses that would merit inquiry and possible sanction by the PSI, while Part 6 sets out the procedures for dealing with complaints, inquiries, and the disciplining of pharmacists. While neither the exact technical competencies required nor procedures for ensuring professional fitness-to-practice for pharmacists are specified in a final form in the 2007 Act, Section 14 1d of the Act makes clear that a requirement for fitness-to-practice must be met on a yearly basis by all practicing pharmacists. This will mean that upon initial registration by the PSI and subsequent annual renewal of registration, pharmacists must satisfy the PSI Council that they are fit for registration. While this may largely involve a self-declaration procedure, any pharmacist who has been the subject of a complaint that has been upheld by the PSI may be deemed unfit to practice following a hearing. Possible sanctions range from compulsory retraining to permanent removal from the register of pharmacists via High Court proceedings. Several routes by which a pharmacist can be deemed unfit to practice are specified within the Act including ill health and through technical incompetence/malice. In an effort to ensure that pharmacists' skill sets are updated on an ongoing basis, from the end of 2010 onwards, it will be mandatory for a pharmacist to be actively engaged in CPD/CPE as a requirement for their continued registration.

The Pharmacy Act 2007, while being welcomed by the pharmacy community in Ireland, represents a complete framework for the overhauling of pharmacy services but has not yet been fully implemented. To achieve its objective of maintaining high professional standards, protecting the patient population, regulating the pharmacy profession more stringently, and improving accountability, further follow-up legislation will be required. For example, the procedures for assessing fitness-to-practice need to be considered further and resolved. In the forthcoming months, the PSI is expected to announce further details of their approach to monitor fitness-to-practice and professionalism for pharmacists to

allow the commencement of Part 6 of the Act. New regulations that will affect how pharmacy premises are run and regulated came into effect in January 2009. The Pharmacy Ireland 2020 Working Group – a sub-committee established by the PSI to perform a review of pharmacy services in Ireland – published its interim report in April 2008 and presented it to the Irish Minister for Health for consideration. It recommends that pharmacists play significantly expanded role in the delivery of frontline healthcare services in Ireland. Health screening, vaccinations, and management of chronic diseases are identified as areas that could benefit from increased pharmacist-led intervention. It is further proposed by the Pharmacy Ireland 2020 Working Group (2008) that a new category of ‘pharmacist-prescribed’ medicines, that are sold without a doctor’s prescription but are entered onto a patient’s medical record, be introduced in Ireland. However, such recommendations can only be implemented within the context of a robust regulatory framework for expanded pharmacy services in Ireland.

In this article, educational practices that are of particular relevance to the acquisition of professional competency by pharmacy students are reviewed and discussed with a view to prepare the next generation of Irish-trained pharmacists for the fitness-to-practice requirements of the Pharmacy Act 2007 and other changes in the professional role of the pharmacist in Ireland.

Discussion

Educating students for professional practice

For a professional to be deemed fit or unfit to practice, their profession must require some kind of formal accreditation. Invariably, this accreditation depends on academic qualification such as the award of an appropriate degree, but is not generally administered by the academic institutions awarding those degrees, rather by a professional society, regulatory body, or government department. This places the academic sector, most notably the universities, in a unique position of needing to consider professional accreditation and competency in their degree design, while not being responsible for the subsequent registering of competent professionals or the striking off of incompetent practitioners. Thus, fitness-to-practice and professional accreditation requirements will increasingly impinge on undergraduate education and pre-registration processes (Wood 2001; Academic Pharmacy Group 2005; Nathan 2005; Irish Medical Council 2006; Irvine 2006; Salter 2006; Shiwani 2007; Goldie 2008).

There has been much debate within the educational literature as to whether universities involved in educating professionals should teach ‘general principles’ or ‘skills’ (reviewed in Kennedy 1987). One argument in favor of concentration on empirical or theoretical knowledge is that students acquire broader understandings of their particular professional competency such that they are equipped with expertise not just in applying skills, but in knowing when to do so. A common model, which applies to many medical and pharmacy degree courses, is that general principles are delivered in the early phases of the degree course within

their specific disciplines, while practice-orientated skills are largely taught (often via fieldwork) in the latter phases. Potential problems with this approach are that students may fail to merge the knowledge they have acquired in various separate subjects/disciplines and may encounter difficulties in integrating that knowledge into the practical skills they learn at a later stage. In other words, the theory and practice are too far removed from one another for students to relate them successfully.

Teaching methods which purport to overcome these caveats by ‘vertically integrating’ knowledge of theory and practice throughout all degree stages include problem-based learning, systems-based medical education, and case-based legal education. However, these methods are also subject to criticism. For example, many high-profile law firms complain that graduates from top law schools, such as Harvard, that employ the case-based method are deficient in basic legal tasks such as negotiating, sourcing information, and preparing briefs (Stevens 1983). In addition, the case-based method is criticized for not equipping students with a broad understanding of the general principles of law (Thorne 1973).

The transition from theory to practice

The acquisition of expertise that defines a new graduate as a competent professional should ideally involve a thorough understanding of both theory and practice relevant to their chosen field (Kennedy 1987). A particularly important period in this regard is the transition from study to practice. With regard to Irish pharmacy education, this transition occurs in the pre-registration year and strictly speaking, pharmacy graduates are not pharmacists until they have successfully completed what is, in essence, a paid internship year in which their work is supervised by a responsible pharmacist. The problem with internship training as a means for acquiring any professional competence is that it tends to produce highly variable results. The skills learned by the intern in such a situation depend largely on the approach, motivation, and skill of the practicing professional(s) supervising the internship and quality control is difficult to achieve (Kennedy 1987).

For example, a new graduate enrolled in a pre-registration training scheme run by a large chain of pharmacies may participate in many structured educational activities during their internship training, while another trainee working in a small, sole practitioner-run, rural pharmacy could have an entirely different type of experience, learning mainly by immersion or ‘on-the-job’ training. While neither example is necessarily superior, it is unlikely that the professional competencies acquired by these two pre-registration graduates could be directly comparable or equivalent.

This implies that if regulatory bodies deem equivalent competencies to be an important aspect of fitness-to-practice, they must either find a means of assessing those competencies fairly or be involved in the design of educational courses that deliver and assess competencies. However, in healthcare fields, accrediting societies that govern practitioner registration are generally independent of the educational institutions training those professionals. There are valid reasons for the divorcing of these two functions and this independent

regulation is considered desirable. For example, in its role as the pharmacy regulator, the PSI should not overly influence the delivery of pharmacy degrees in Ireland. While it does assess the attainment of professional competency to some extent by setting a written examination and accrediting the Irish degree programs, it does not really ensure that Irish-trained pharmacists acquire technical competencies in a standardized way and in essence, it does not assess technical skills at all before deeming someone fit-to-practice as a pharmacist.

In view of the new fitness-to practice requirements within the 2007 Pharmacy Act, the PSI in collaboration with pharmacy educators needs to find a means of standardizing the acquisition of professional competencies by pharmacy students and/or graduates. The Pharmacy Act 2007 significantly broadened the remit of the PSI in this regard and prompted them to commission a root and branch review of the overall 5-year program of pharmacy education and training in Ireland. The Pharmacy Practice Research Group of the School of Pharmacy, Aston University (UK), was commissioned to conduct the Pharmacy Education and Accreditation Reviews (PEARs) project. They are due to produce their final recommendations by early 2010, with interim reports in the meantime, and their main remit is to review and devise criteria for accreditation of the fifth pre-registration training year. One possibility they are considering is to incorporate the pre-registration year into the undergraduate degree so that it takes on a more structured form that is essentially run by the universities themselves (Pharmaceutical Society of Ireland 2009a). This could possibly be based on the 'clerkship' model, common in the US, which is discussed below (Shaw 2002).

Competency-based training and assessment of pharmacists

An alternative approach would be for the three Irish pharmacy schools to alter their undergraduate teaching and assessment methods so that new graduates are certified as being fit-to-practice upon graduation. This approach would rely on assessing the attainment of professional competencies in addition to, or instead of, academic performance in subjects/disciplines.

Competency-based assessment measures the performance of individual students in practical tasks against previously defined standards, thereby requiring students to apply theoretical knowledge to the clinical situation within a realistic context. There have been several attempts to develop competency-based assessment in pharmacy training at both undergraduate and post-qualification levels (Davies et al. 2002; McRobbie et al. 2002; Merrigan 2002; Goldsmith et al. 2003; Hill et al. 2006; Kelley & Demb 2006; Turner et al. 2006; McMahon & Henman 2007; Duke et al. 2008; Petit & Foriers 2008; Pflieger et al. 2008). Within the US, the implementation of competency-based assessments has been largely focused on the experiential, latter portion of the course, with other subjects being examined by more traditional examination methods. At Virginia Commonwealth University, for example, a consultative process revealed that both students and faculty members were positive about competency assessment and

that the new process was effective at preparing pharmacy students for practice (Hill et al. 2006). However, in another study in which the perceptions of competency-based assessment were compared between undergraduate PharmD students and their educators, students tended to overestimate their achievement of competencies in comparison to staff members (Kelley & Demb 2006). A unifying theme in these studies is that major driving forces in competency-based assessment must be curriculum reform in response to student/staff perceptions and accountability with regard to accreditation requirements for pharmacists.

In the Irish context, the TCD-based MSc in Hospital Pharmacy has recently introduced competency-based assessment of student skill sets. Overall, this approach was deemed successful with students generally achieving certain competencies at rates proportional to their prior experience levels (McMahon & Henman 2007). However, it should be noted that those students had significant experience in their chosen field of pharmacy and applying the same methodology to inexperienced undergraduates would not necessarily be so successful. Perhaps, a more realistic approach would be to introduce the concept of competency-based assessment early in the Irish undergraduate degree, with modest goals, and to gradually increase the contribution of competency-based assessment as the degree proceeds with a concomitant reduction in emphasis on traditional teaching and assessment methods (e.g., didactic teaching and written examinations). To this end, communication skills and professional acculturation modules, that include problem-based learning and exemplify this approach, have already been introduced in the early years of the TCD degree.

Competency-based assessment of practical pharmacy skills, however, would almost certainly require extensive, structured work placement periods within the 4-year degrees. Arguably, if these were to occur while maintaining academic rigor and standards in the traditional pharmacy disciplines, either students would need to sacrifice some existing holiday time or Irish degrees would require lengthening. Neither is likely to be a popular option. A further possibility is to identify and eliminate aspects of Irish pharmacy degrees that are not crucial for the attainment of professional competencies. It has been suggested that since final-year research projects consume significant hours in UK-based pharmacy degrees but are diverse in their nature and quality, they may be of limited value and could be shortened or eliminated in favor of more structured training in research methodologies and professional acculturation (Wilson et al. 2006; Langley et al. 2007).

Moreover, assessing professional competencies rather than academic performance presents problems in selecting those competencies to be assessed (McRobbie et al. 2002; Davies et al. 2002; Baker 2006; Pflieger et al. 2008). Pharmaceutical assessors working in the Irish Medicines Board, community, hospital and academic pharmacists, and pharmacists working in the pharmaceutical industry perform very different jobs and require diverse competencies and skill sets. Yet, large numbers of Irish-trained pharmacists perform all of these roles and indeed similarly diverse roles abroad. It is unrealistic to expect a school leaver in the course of a 4-year or even 5-year degree program to acquire sufficient skills that they would be

fit-to-practice in all of these distinct areas of pharmacy upon graduation. But it is arguably the responsibility of an educational institution to educate pharmacists for every area of pharmacy, rather than train them for particular job roles or simply to dispense (Florence 2002; Mullen et al. 2003; Florence 2004; Wilson et al. 2005). So, who should decide on what core professional competencies are required for someone to be deemed fit-to-practice as a pharmacist and entitled to PSI registration? What proportion of more specialist skills can be subsequently acquired through continuous professional education, on-the-job training, and experience? Is it appropriate that all pharmacists will have to participate in CPE/CPD if they wish their fitness-to-practice and registration to be renewed at yearly intervals and if so, how much CPE/CPD should be required? Do we need new registration procedures for pharmacists in Ireland or across countries so that sub-specialties can be recognized, similar to the registration procedures that exist for specialist doctors?

While there are no clear-cut answers, it is obvious that reaching a solution that is acceptable to all stakeholders – the PSI, educators, students, existing practitioners, tutor pharmacists, the public at large, and patients – will require extensive consultation and novel thinking. Nowadays, the implementation of radical changes in any aspect of healthcare requires that international experience and best practice is considered and informs major decisions. Current and future undergraduates, who cannot control the process *per se*, will be represented by their educators in this debate, and it is crucial that their undergraduate education at least prepares them (if not actually qualifying them) for the fitness-to-practice requirements they will be challenged with upon graduation. To this end, academic pharmacists, other academic staff, and pharmacist teacher-practitioners must fully embrace the process of re-designing Irish pharmacy education for the twenty-first century. Moreover, they must do so with a view to best practice from abroad.

Adapting undergraduate pharmacy education to overcome new challenges: International comparisons

The World Health Organisation (WHO) issued a seminal report on the international standardization of pharmacy education in which they proposed the professional acculturation of a 'Seven-Star Pharmacist' who would be a care-giver, decision-maker, communicator, leader, manager, life-long learner, and teacher (World Health Organisation 1998). Furthermore, they identified a greater focus on active student learning, the development of problem-solving and critical thinking skills, and the use of educational technologies as key factors that educators must embrace in the evolution of pharmacy education. However, international comparisons across pharmacy degrees are difficult, not least because of differences in their nominal qualifications. For example, entry-level BSc, BPharm, MPharm, and DPharm degrees that are remarkably similar in academic content, now exist in different countries.

A detailed comparison of undergraduate pharmacy education in New Zealand (Otago) and the University of North

Carolina (UNC; General Medical Council 2007) highlighted both similarities and differences between the 'American' and British/European models of pharmacy education (Shaw 2002). Shaw identified the clerkship model adopted in UNC, in which students rotate through several practice sites, undertaking a series of pharmacy 'clerkships' within their degree programs as a more comprehensive preparation for future practice than the New Zealand/European systems whereby academic and experiential components (i.e., pre-registration training) are almost completely separate. Clerkship training means that students experience many more areas of practice (e.g., hospital, community, ambulatory care, general medicine, oncology, and pediatrics) prior to registration, and there is good integration of taught courses and practice experiences by virtue of a large number of teacher practitioners in the system.

Survey-based studies of undergraduate pharmacy curricula and pharmacy students' attitudes toward their acquisition of a professional identity suggest that in the UK, pharmaceutical sciences still dominate the first 2–3 years of the degree and that students' generally accept this to be a necessary foundation prior to their professional acculturation in the latter stages of their degree (Florence 2004; Wilson et al. 2005; Wilson et al. 2006). However, disadvantages to this approach reported by students and perceived by educators include their use of surface learning techniques to accumulate scientific knowledge and insufficient exposure to pharmacy practice in the early stages of the degree (Florence 2002; McRobbie 2004; Taylor 2007). A further problem, that is exacerbated in countries in which pharmacy student numbers are increasing (including Ireland), is the reduced opportunities for students to engage with practicing pharmacists, since recruitment issues mean that a growing proportion of academic staff within pharmacy schools are not actually trained pharmacists (Taylor & Harding 2002; Taylor et al. 2004). As outlined in the UNC example, competency-based assessment relies heavily on the involvement of teacher-practitioners – whom students consider to be professional role models. A survey of UK academics also suggested that while educators are generally supportive of a move away from didactic teaching and toward the concept of a 'knowledge, skills and attitudes' map for pharmacy education in line with new legal fitness-to-practice requirements similar to those in Ireland, resources were considered to be a major stumbling block (Wilson et al. 2006). It is difficult to see how Irish universities can realistically be expected to incorporate a significant amount of competency-based assessment and professional acculturation into their degree programs without financial and logistical support for the provision of many teacher-practitioner posts, very few of which exist currently in Ireland. This challenge comes at a time when Irish universities are facing a funding crisis and have been asked by their education minister to cut their expenditure significantly this year. According to the OECD, in a strong period of economic growth, the number of students in Irish universities rose considerably while government funding failed to keep pace with this growth in student numbers, such that there has been a very significant drop in resources per student in real terms over the last decade (Irish Universities Association 2008).

This problem is now exacerbated by the deep recession currently being experienced by Ireland and much of the developed world.

Conclusions and future directions

Incorporating fitness-to-practice requirements into the new Pharmacy Act has radical implications for the registration, regulation, and sanctioning of pharmacists in Ireland and must be introduced effectively, sensitively, and with a view to preparing future pharmacists for its implementation. While pharmacy training will always, necessarily, be built on a strong scientific background (Florence 2002; Florence 2004), the new fitness-to-practice requirements provide an opportunity to review the balance of practice and science in undergraduate curricula and the teaching methods by which they are delivered (Davies et al. 2002; McRobbie 2004; Academic Pharmacy Group 2005; Wilson et al. 2005; Jesson et al. 2006; Taylor 2007). Novel teaching and assessment methods such as competency-based assessment, that are more focused on professional acculturation and the training of competent practitioners, may equip Irish pharmacy graduates more thoroughly for the new legal requirements (World Health Organisation 1998; Davies et al. 2002; Merrigan 2002; Goldsmith et al. 2003; Hill et al. 2006; Turner et al. 2006; Taylor 2007; Goldie 2008; Petit & Foriers 2008). However, educators must not lose sight of their academic freedom and responsibility in providing a broad and academically rigorous educational experience that equips their students to work in many areas of pharmacy, science, education, and beyond. Consultation with students, the PSI, and other stakeholders, may help to improve the delivery of pharmacy degrees and achieve the right balance in this regard. International comparisons suggest that the pre-registration training model currently in place in Ireland could be improved by the implementation of a more structured, rotational system, similar to that operating in the US (Shaw 2002). However, if this results in the extension of the Irish pharmacy degree, there will be major financial and resource implications for both trainees and educational institutions. It is imperative for the Irish Government to invest sufficient resources in Irish pharmacy education thereby allowing pharmacists to fulfill their desired expanded professional roles at the frontline of Irish healthcare.

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