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COVID-19 related regulatory change for pharmacists – The case for its retention post the pandemic

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ABSTRACT

The delivery of healthcare including the provision of pharmacy services globally is highly regulated internationally in order to protect public health and welfare. However, the onset of the COVID-19 pandemic has precipitated the need internationally to amend the model of regulation in order to ensure that people were able to continue to access a range of healthcare services in a timely and effective manner. Many of the changes introduced to the regulation of pharmacy services in Ireland have been replicated in other countries. These include the introduction of electronic means to transmit prescriptions and other orders for medications, relaxing the legal restrictions in place controlling the emergency supply of prescription only medicines and more fully utilizing the professional competency of pharmacists by empowering them to use their expertise and judgment to support their patients accessing the healthcare services that they need. Many of the regulatory changes that have been introduced to support the COVID-19 public health emergency effort are ones that pharmacists have previously sought to enable them provide a more effective and expanded model of pharmaceutical care to their patients. Accordingly, many pharmacists will want these regulatory changes to be retained and further expanded in the aftermath of the COVID-19 public health emergency in order to extend their scope of practice and support them in the care of their patients.

Introduction

From the outset of the current COVID-19 pandemic in December 2019, healthcare professionals worldwide have responded in diverse ways to ensure the safety and optimal care of patients infected with the virus, and those at risk of infection. In the early stages of the pandemic, confusion resulted in some patients self-administering medications with putative benefit to treat the infection and in others, interrupting their prescribed medications for chronic illnesses due to fear of adverse effects, with the potential to cause patient morbidity. Many of these were driven by social media reports advocating positive aspects of some therapies, and negative consequences of on-going administration of others, often fueled by misinformation channeled through the COVID-19 infodemic.^{1–4} Drug shortages resulting from buying unnecessary and excessive quantities of medicines were also common until rationalization and commonsense prevailed on evidence-based advice.^{1,5–8}

With patient safety a priority, the practice and delivery of healthcare in Ireland and internationally has responded, taken action and adapted

to the impact of the pandemic, including that of the practice of pharmacy in the hospital and community settings. Hospital pharmacy initiatives centered on comprehensive medicines management protocols and guidelines, re-organization of hospital services and practical changes to the hospital layout in addition to the upskilling of clinical pharmacists.^{9–14} Both sectors were required to minimize the potential infection risk to both themselves and their patients resulting in marked changes in staffing (e.g. formation of staff pods), the use of precautionary personal protective equipment, changes to pharmacy floor layouts to ensure social distancing was maintained and innovative communication strategies between patients and fellow healthcare workers.^{15–20} The potential for targeted community pharmacy activities were highlighted shortly after the country went into preventive lockdown.²¹ The drivers and barriers to adapting community pharmacy services in the face of the pandemic has recently been reported by Hoti et al. and provides an indication of the need for policymakers and regulatory authorities to address the needs of community pharmacies to ensure better delivery of pharmacy services in the community.²²

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Telehealth and telemedicine healthcare initiatives to maintain patient care have flourished during the pandemic and may be the precursor for sustained change.^{23–29} This may also be emulated in the community pharmacy setting where telepharmacy or telehealth consultations may become the 'new normal'.^{23,30} However, such initiatives will inevitably require changes to current legal frameworks in place to regulate the delivery of pharmacy services.

Changes to the delivery of pharmacy services in light of the emerging pandemic situation were reactionary, dynamic and innovative to ensure patients continued to have access to their medicines. Governments responded to ensure that deviations from the existing legal requirements regulating the supply of medicines were not necessitated by introducing changes to the legal frameworks regulating the provision of medications in the primary care setting, to ensure and prioritize seamless supply to patients.

Regulatory changes prompted by the COVID-19 pandemic in Ireland

In Ireland, the profession and practice of pharmacy is subject to significant regulation, principally in accordance with the provisions of the Pharmacy Act 2007 as is the case internationally.³¹ Under the Act, the Pharmaceutical Society of Ireland (PSI) is charged with the enforcement of its provisions. The practice of pharmacy is also subject to a range of associated laws regulating the sale and supply of medicines and the PSI is also charged with their enforcement in respect of retail pharmacy businesses registered with it.

Temporary restoration to the Register of Pharmacists

The Irish parliament introduced the Emergency Measures in the Public Interest (COVID-19) Act in March 2020.³² This wide-ranging Act introduced provisions to address issues relating to the pandemic including the operation of residential tenancies, planning and development and the introduction of a temporary wage subsidy. In order to address shortages in key frontline healthcare personnel as a result of the pandemic, it also included provisions to allow healthcare professionals including pharmacists, doctors, nurses and dentists who were previously registered with the relevant regulatory authority but who wished return to professional practice to assist with the pandemic effort, to renew their registration quickly and efficiently. In relation to pharmacists, Section 12 of the Act amended the Pharmacy Act 2007 to introduce a new section to it, Section 77, which allowed previously registered pharmacists who were no longer registered, to be restored temporarily to the Register of Pharmacists in Ireland.³² The usual fee payable by those previously registered pharmacists applying to be restored to the Register of Pharmacists was waived for those applying under the newly introduced Section 77. The PSI has confirmed that a total of 38 pharmacists were restored to the Register of Pharmacists under Section 77 to June 30, 2020. The period of registration for any pharmacist re-registered under Section 77 of the Pharmacy Act is due to expire on July 31, 2020. However, the Minister for Health is empowered under the Emergency Measures Act to extend that date by Ministerial order.

Changes to the supply of medicines

The sale and supply of medicines in Ireland is primarily regulated by two sets of Regulations as follows. The Medicinal Products (Prescription & Control of Supply) Regulations 2003 as amended regulates both the prescribing and the supply of medicines to the public in Ireland, in accordance with the requirements of the European Union's Framework Directive 2001/83/EC relating to medicinal products for human use, insofar as they relate to the classification for supply for human use.³³ The Misuse of Drugs Regulations 2017 as amended apply additional controls to medicinal products to which the provisions of the Misuse of Drugs Acts 1977 to 2016 apply i.e. controlled drugs.³⁴

As part of a range of health-related measures introduced in Ireland in response to the COVID-19 pandemic, in March 2020 the Minister for Health signed into law the Medicinal Products (Prescription & Control of Supply) (Amendment) Regulations 2020 and the Misuse of Drugs (Amendment) Regulations 2020.^{35,36} The key changes introduced in both these amending regulations focused on maintaining the supply of, and access to, medicines by patients. They introduced significant changes which saw both an easing of the regulatory controls previously in place on the prescribing and supply of medicines and an enhanced professional role for pharmacists.

The changes in the Medicinal Products (Prescription & Control of Supply) (Amendment) Regulations achieve this through a range of means including (Table 1)³⁵:

- i. Permitting the electronic transmission of prescriptions to pharmacies via the National Electronic Prescription Transfer System (NEPTS) by prescribing practitioners for the first time.
- ii. Extending the validity of prescriptions issued (other than for controlled drugs listed in Schedules 2 or 3 of the Misuse of Drugs Regulations) from six to nine months.
- iii. Increasing the permitted number of occasions in which a pharmacist can lawfully repeat a prescription according to the schedule in which the drug appears in the Regulations (other than for controlled drugs listed in Schedules 2, 3 or 4 Part 1 in the Misuse of Drugs Regulations).
- iv. Increasing the quantity of a prescription only medicine (POM), other than a controlled drug, that can be supplied at the request of a patient without having a valid prescription in an emergency from a maximum of 5 days' supply to 10 days' supply.
- v. In an emergency, a pharmacist may now provide up to 5 days' supply of a controlled drug to a patient at either the request of a patient or a practitioner.

Prior to the introduction of the Misuse of Drugs (Amendment) Regulations in Ireland, there were strict requirements regarding the form of prescriptions for controlled drugs.³⁶ In addition to the requirement for an original hardcopy prescription, there were specific requirements for controlled drugs in Schedule 2 and 3 that had to be in the prescribing practitioner's own handwriting including the name of the controlled drug being prescribed and the total quantity of it to be supplied in both words and figures. However, the extension of the NEPTS to prescriptions for controlled drugs in Schedules 2 & 3 of the Regulations mean that prescriptions for controlled drugs no longer have to be furnished to the pharmacist for dispensing in the original hard copy form with specific details written in the prescribing practitioner's handwriting. The changes introduced by the Misuse of Drugs (Amendment) Regulations 2020 are summarized in Table 2.

A summary of the changes to the regulations were provided to all community pharmacists by the PSI in addition to other advice and guidance.³⁷

Discussion

The public health emergency that presented with COVID-19 required national governments across the world to rapidly introduce a range of regulatory measures to address not only its containment, but to make appropriate provision for its citizens whose ability to engage in normal daily activities such as working and obtaining essential supplies were severely curtailed. In Ireland, the introduction of the Emergency Measures in the Public Interest (COVID-19) Act in March 2020 was a key legislative response in this regard, making appropriate provision in areas as diverse as residential tenancy agreements, temporary wage subsidies for those whose employment was interrupted by the pandemic, redundancy payments, civil registration and statutory review periods under the Mental Health Act.³² The Act also included provisions to expedite the process already provided for in various Acts for previously

Table 1

Summary of the changes introduced through the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020.^{35,37}

Regulatory Provision	Change Introduced	Corresponding Pre Covid-19 Provision
Form of Prescription	The introduction of the National Electronic Prescription Transfer System permitting the electronic transfer of a prescription by the prescriber to the dispensing pharmacy	An original hard copy of the prescription, dated and signed by the prescriber with their original signature which was furnished to the dispensing pharmacy
Period of Validity of Prescription (provided drug not listed in Schedules 2 or 3 of Misuse of Drugs Regulations)	9 months from the date specified thereon by prescriber, where in the pharmacist's professional judgment, having consulted with the patient and prescriber as appropriate, continued treatment is required and it is safe and appropriate to do so.	6 months from the date specified thereon by prescriber
Repeat Supply i.e. No. of occasions a prescription may be dispensed		
i Prescription containing non-renewable S1A medicine ^a (not a drug listed in Schedules 2, 3 or 4 Part 1 in Misuse of Drugs Regulations) where prescriber does not specify no. of occasions or intervals that it may be repeated	May be repeated once where the pharmacist considers it appropriate and necessary for the continued treatment of the person and it is unreasonable in the COVID19 circumstances to require the person to get a new prescription	May only be dispensed on one occasion only i.e. may not be repeated.
ii Prescription containing non-renewable S1A medicine (not a drug listed in Schedules 2, 3 or 4 Part 1 in Misuse of Drugs Regulations) prescribed on a health (GMS) prescription form and is not ordinarily endorsed by the prescriber to be repeated	Can be dispensed on up to a total of four occasions where in the opinion of the pharmacist it is appropriate and necessary for the continued treatment of the person for further supplies to be made	May only be dispensed on one occasion only i.e. may not be repeated
iii Prescription for non-renewable S1A medicine which indicates the intervals that it can be supplied but not the no. of occasions	May be dispensed on up to a total of four occasions	Can be dispensed on up to a total of three occasions
iv Prescription for non-renewable S1A medicine which indicates the number of occasions that it can be supplied but not the intervals	May be dispensed on the no. of occasions indicated on the prescription at such intervals as the pharmacist considers appropriate having due regard to the specified dose rate up to the maximum 9 month period of validity of the prescription from the date specified thereon.	May be dispensed on the no. of occasions indicated on the prescription at such intervals as the pharmacist considers appropriate having due regard to the specified dose rate up to the expiry of the prescription 6 months from the date specified thereon
v Prescription for renewable S1B ^b medicine which does not indicate either the number of occasions or the intervals that it may be supplied	May be supplied by the pharmacist for up to 9 months from the date specified on the prescription on the no. of occasions that the pharmacist considers appropriate, where it is their opinion that it is appropriate & necessary for the continued treatment of the patient	May be supplied by the pharmacist for up to 6 months from the date specified on the prescription as the pharmacist considers appropriate having regard to the specified rate of dosage.
vi Prescription for renewable S1B medicine which states the intervals that it may be supplied but does not indicate the no. of occasions	May be supplied by the pharmacist for up to 9 months from the date specified on the prescription at the intervals stated on the prescription	May be supplied by the pharmacist for up to 6 months from the date specified on the prescription at the intervals stated on the prescription
vii Prescription for renewable S1B medicine which states the no. of occasions it can be supplied but not the intervals	May be supplied for the specified number of occasions at such intervals that the pharmacist considers appropriate, having regard to the specified dose rate and period of validity of the prescription (9 months from the date specified thereon)	May be supplied for the specified number of occasions at such intervals that the pharmacist considers appropriate, having regard to the specified dose rate and period of validity of the prescription (6 months from the date specified thereon)
viii Prescription for either S1A or S1B medicine where the no. of occasions specified for its supply have been reached	May be dispensed on three further occasions where in the opinion of the pharmacist it is appropriate and necessary for the continued treatment of the person for further supplies to be made	No further supplies could be made by the pharmacist
Emergency Supply of a Prescription Only Medicine (POM) at the Request of a Patient	<ol style="list-style-type: none"> Where the qualifying conditions are met, and in their opinion, it is safe, appropriate and necessary for the patient's continued treatment to make the emergency supply. A pharmacist can dispense up to 10 days' supply of a POM If the POM required contains a drug listed in Schedules 2,3 or 4 of the Misuse of Drugs Regulations (controlled drug), up to 5 days' supply can be dispensed provided the pharmacist is satisfied that due to Covid 19 circumstances, it is unreasonable for person to obtain a prescription and in their opinion, it is safe, appropriate and necessary for the patient's continued treatment to make the emergency supply. Up to 10 days' supply of the following drugs listed in Schedule 4 of the Misuse of Drugs Regulations can be supplied for the treatment of epilepsy: midazolam; clobazam and clonazepam. 	<ol style="list-style-type: none"> Where the qualifying conditions were met, a pharmacist could dispense up to 5 days' supply of a POM If the POM requested by the patient contained a drug listed in Schedules 2,3 or 4 of the Misuse of Drugs Regulations, no emergency supply could be dispensed with the exception of phenobarbitone, phenobarbitone sodium and methylphenobarbitone for the treatment of epilepsy. Up to 5 days' supply of the following drugs listed in Schedule 3 of the Misuse of Drugs Regulations could be supplied for the treatment of epilepsy: phenobarbitone, phenobarbitone sodium and methylphenobarbitone.
Emergency Supply at the Request of a Prescriber	<ol style="list-style-type: none"> If the POM requested by the prescriber contains a drug listed in Schedules 2,3 or 4 of the Misuse of Drugs Regulations, up to 5 days' supply can be dispensed provided the pharmacist is satisfied that due to Covid 19 circumstances, it is unreasonable for person to obtain a prescription and in their opinion, it is safe, appropriate and necessary for the patient's continued treatment to make the emergency supply An emergency supply (quantity not limited) of the following drugs listed in Schedule 4 of the Misuse of Drugs Regulations can be supplied for the treatment of epilepsy: midazolam; clobazam and clonazepam 	<ol style="list-style-type: none"> If the POM requested by prescriber contained a drug listed in Schedules 2,3 or 4 of the Misuse of Drugs Regulations, no emergency supply could be dispensed with the exception of phenobarbitone, phenobarbitone sodium and methylphenobarbitone for the treatment of epilepsy. An emergency supply (quantity not limited) of the following drugs listed in Schedule 3 of the Misuse of Drugs Regulations could be supplied for the treatment of epilepsy: phenobarbitone, phenobarbitone sodium and methylphenobarbitone.

^a S1A- Medicinal products contained in Schedule 1 Part A of the Medicinal Products (Prescription & Control of Supply) Regulations 2003 as amended.^b S1B -Medicinal products contained in Schedule 1 Part B of the Medicinal Products (Prescription & Control of Supply) Regulations 2003 as amended.

registered pharmacists, doctors, nurses, midwives, dentists and other health and social care professionals to be restored to the Register and in a position to practice their profession.

This regulatory initiative complemented the recruitment initiative “Be on call for Ireland” launched in March 2020 by the Health Service Executive (HSE) in Ireland.³⁸ “Be on call for Ireland” was introduced to recruit additional healthcare professionals across a range of disciplines to address the expected deficit in the personnel available to provide the additional care required as a result of COVID-19. Over 72,000 people responded to the initiative and by May 2020, over 1600 additional healthcare professionals were either working or about to start work in the Irish healthcare service.³⁹ Healthcare professionals who re-registered under provisions introduced by the Emergency Measures in the Public Interest (COVID-19) Act, including pharmacists under the newly introduced Section 77 of the Pharmacy Act 2007, did so free of charge but their registration was temporary and was due to expire on July 31, 2020. The Minister for Health, however, is empowered under the Act to set a different date for the expiry of these temporary registrations. It is expected that the Minister will extend this on one further occasion to the end of December 2020 to reflect the ongoing public health emergency related to COVID-19 and the continued need to have additional healthcare professionals available to assist with the associated demand for healthcare.

Cadogan & Hughes identified a range of roles and functions that community pharmacists could play during the pandemic.²¹ They noted maintaining the continuity of pharmacy services including supplies of essential medicines as one of these key functions. Guidance from the International Pharmaceutical Federation provided recommendations across a broad range of pharmacy roles to assist the execution of these functions.¹⁵ The need for the granting of greater authority to community pharmacists by governments to ensure that such roles could be undertaken legally was recognized. In their comprehensive review of pharmacy community activities relating to COVID-19 across several jurisdictions, Merks et al. concluded that the fundamental role of the pharmacist, even in a pandemic, continued to be to dispense prescriptions and to ensure uninterrupted access to medicines and identified the legislative changes undertaken to allow this.⁴⁰ In Ireland, the regulatory changes introduced by both the Medicinal Products (Prescription & Control of Supply) (Amendment) Regulations and the Misuse of Drugs (Amendment) Regulations, are exclusively focused on maintaining essential supplies of medicines to patients throughout the period of the pandemic.^{35,36}

Permitting the electronic transmission of prescriptions to pharmacies by prescribing practitioners for the first time represents a considerable change in the regulations in Ireland around the supply of medicines. This was prompted to ensure protection of the public and compliance with the strict lockdown initiatives taken to prevent community transmission of the virus. Heretofore, a pharmacist could only lawfully supply a POM by the patient presenting an original hard copy of their prescription with the original signature of the practitioner in the pharmacy. Under the amended regulations, however, only electronic prescriptions that are sent via the NEPTS established under the Regulations are valid. Prescriptions electronically transferred using another electronic means or faxed to pharmacies are not valid and cannot be lawfully dispensed by the pharmacy. While the NEPTS introduced an effective means of transferring prescriptions to pharmacies to ensure patients got their

medicines during the pandemic, it does not constitute the introduction of a national centralized electronic prescribing system (e-prescribing) as envisioned by Ireland’s National eHealth Strategy and the 2018 Health Information and Quality Authority review on e-prescribing.^{41,42} Austria and Italy have also introduced systems of electronic prescriptions in response to the emerging circumstances of the COVID-19 pandemic.⁴⁰ A recently published survey of Dutch pharmacists noted a preference for electronic prescriptions to ensure that direct patient contact was limited, while the Australian government provided a significant monetary package to reduce the community’s risk of exposure to infection, including electronic prescribing for general practitioners.^{16,19} In Ireland, the electronic transfer of prescriptions has been facilitated by Health-mail during the pandemic and both the Hospital Pharmacists Association of Ireland (HPAI) and Irish Medication Safety Network (IMSN) are advocating the retention of this method of transfer of prescriptions, which reduces the risk of medication errors at transitions of care.

Increasing the period of validity from six to nine months during which a pharmacist can lawfully repeat a prescription according to the schedule in which the drug appears in the Regulations (other than for controlled drugs listed in Schedules 2 or 3 in the Misuse of Drugs Regulations) was an additional initiative aimed at minimizing the need for patients to return to their general practitioner (GP) to have a fresh prescription issued.³⁵ This was also the impetus behind increasing the quantity of a POM (other than a controlled drug) that can be supplied at the request of a patient without having a valid prescription in an emergency from a maximum of 5 days’ supply to a maximum of 10 days’ supply. Cadogan & Hughes noted that in the circumstances of the pandemic, the duration of supply permitted in an emergency at the request of a patient may need to be extended beyond a maximum of 5 days’ supply (21). Similar changes in the legal requirements were introduced in several countries including Canada and France and were aimed at limiting interactions between members of the public and prescribing practitioners, and the need for older persons to be shielded to minimize infection risk (40).

Heretofore, controlled drugs specified in Schedules 2, 3 and 4 of the Misuse of Drugs Regulations could not be supplied without a valid prescription in any circumstances, at either the request of a practitioner or a patient, with the exception of specified phenobarbitone drugs for the treatment of epilepsy. Under the amending Regulations, a pharmacist, provided the usual qualifying conditions for an emergency supply are satisfied, may now provide up to 5 days’ supply of a controlled drug to a patient at either the request of the patient or a practitioner.³⁶ In the case of midazolam, clobazam and clonazepam, which are all listed in Schedule 4 of the Misuse of Drugs Regulations, where they are required for the treatment of epilepsy in an emergency, a pharmacist may lawfully provide up to 10 days’ supply at the request of a patient and at the request of a practitioner the quantity specified (not limited) by them. In Great Britain and in Northern Ireland, while legislation has been introduced allowing for the emergency supply of controlled drugs at the request of a patient, (The Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of Controlled Drugs During a Pandemic etc.) Regulations 2020 in Great Britain and The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2020), the relevant provisions therein have not been invoked.^{43,44} No additional specific changes were introduced to the provision of controlled drugs to treat persons with substance misuse disorders in Ireland during the pandemic. Some

Table 2
Misuse of Drugs (Amendment) Regulations amended 2020.^{36,37}

Regulatory Provision	Change Introduced	Corresponding Pre Covid-19 Provision
Form of prescription	The introduction of the National Electronic Prescription Transfer System permitting the electronic transfer of a prescription for a controlled drug in Schedules 2, 3 & 4 of the Misuse of Drugs Regulations by the prescriber to the dispensing pharmacy	An original hard copy of the prescription, with specific requirements that had to be in the prescriber’s handwriting (for drugs listed in Schedules 2 & 3 of the Regulations) along with being dated and signed by them with their original signature which was furnished to the dispensing pharmacy

relaxation in such regulatory requirements was provided for in the US and subsequently, calls have been made to maintain these changes to enhance the role of pharmacists in provision of care to this vulnerable population.^{45,46}

The regulatory changes relating to the supply of medicines represent a significant easing of the legal requirements that existed heretofore in Ireland and it can reasonably be concluded that they have made an important contribution to ensuring that patients have been able to maintain access to the medicines they require during the ongoing pandemic. The Irish Pharmacy Union (IPU) which represents the interests of community pharmacists in Ireland has indicated that the regulatory changes introduced have worked well for patients.⁴⁷ In the future, it will be important to engage with the relevant stakeholders including pharmacists, patients and policy makers to assess whether these and other measures put in place in response to the emerging COVID-19 situation were effective so that it can appropriately inform the response required in future public health emergencies.²¹

Prior to the regulatory changes precipitated by the pandemic, the perceptions of community pharmacists in Ireland of the model in place to regulate their practice as provided by the Pharmacy Act 2007 and associated regulations including those in place to regulate the sale and supply of medicines, were researched.⁴⁸ This study explored the “lived experience” of pharmacists in community practice with the model of regulation as implemented and enforced by the PSI and their perception of it as fulfilling the seven principles of “better regulation”: Necessity; Effectiveness/Targeted; Proportionality; Transparency; Accountability; Consistency and Agility.^{48–50} In summary, the model of regulation and its implementation by the PSI was not perceived overall by community pharmacists as fulfilling the principles of better regulation. While there was agreement that the Act and associated regulation was necessary, its implementation by the PSI was not viewed as being effective, targeted, proportional and consistent. The Act was not sufficiently agile to respond to changes in pharmacy practice.

In terms of fulfilling the principles of “better regulation”, the amendments to both the Medicinal Products and Misuse of Drugs Regulations can be reasonably considered to fulfil the “better regulation” principles of: necessity; effectiveness/targeted; proportionality and agility. As the public health emergency unfolded, these regulatory changes were necessary in order to ensure the continuity of supply of medicines to patients. They are effective insofar as they are appropriately targeted at maintaining the medicines supply chain and proportional in that there does not appear to have been an alternative regulatory approach available to achieving the required public health outcome. Agile regulation is concerned with being able to look forward to the future and being able to anticipate change and adapt accordingly.⁵⁰ As reported by Merks et al., the range of regulatory changes introduced internationally in the sphere of pharmacy practice, together with the various legislative changes in Ireland in response to the emergence of the COVID-19 pandemic, epitomize the concept of agility in regulation.⁴⁰ However, agile regulation heretofore has not been perceived as a feature of the regulation of pharmacy in Ireland by community pharmacists.⁴⁸ The model of regulation of pharmacy in Ireland was generally viewed as being rigid and unable to readily respond to emergent changes in pharmacy practice, such as societal and technological developments that have an impact on the delivery of pharmacy services. Preliminary findings from a more extensive and ongoing follow-up study commenced in early 2020 surveying the views of a wider cohort of community pharmacists, appear to confirm this view, particularly in areas such as information technology.⁵¹ In relation to electronic prescribing, one respondent noted “*We still have to chase doctors for original paper prescriptions, they don't understand that their email, fax, phone call is not enough and get annoyed by our hounding*”.

Neither the Medicinal Products (Prescription & Control of Supply) (Amendment) Regulations or the Misuse of Drugs (Amendment) Regulations of 2020 include a “sunset clause” i.e. date when they will cease to have effect. In the explanatory note included with the Medicinal

Products Regulations, outlining the rationale for their introduction, it states that the purpose of the regulation is to introduce ‘temporary’ measures to address the COVID-19 emergency.³⁵ However, the explanatory notes for the Misuse of Drugs Regulations does not indicate that the measures are temporary or otherwise.³⁶ Accordingly, it is not clear whether the various amending provisions contained in both Regulations are intended to be revoked once the COVID-19 emergency ends. This is likely to be of concern to pharmacists in Ireland because many of the changes that have been introduced may be viewed as progressive and supporting pharmacists to provide an optimal service to their patients. The recent introduction of the NEPTS in the Medicinal Products (Amendment) Regulations has been welcomed by the IPU but has been described by it as only a first step towards an appropriate e-prescribing system.⁴⁷ Having introduced the service, it would appear inconceivable for it to be revoked once the COVID-19 emergency is over, with many pharmacists likely to advocate its further expansion to a fully developed and functioning centralized e-prescribing system that replaces the current widespread reliance on the issuance of original hard-copy prescriptions in order for them to lawfully supply POMs.

As part of its powers under the Pharmacy Act, the regulatory authority for pharmacy in Ireland, the PSI is authorized to enforce the laws regulating the supply of medicines including both the Medicinal Products and Misuse of Drugs Regulations. It has been reported that community pharmacists perceive the PSI as requiring an absolute standard of best practice that was not commensurate with the practicalities of providing front-line pharmacy services.⁴⁸ They viewed the PSI as enforcing a series of rigid “black & white” requirements that fail to acknowledge the need for pharmacists to apply discretion to act in the best interests of their patients. Some of the legal requirements informing this viewpoint was the inability of a pharmacist to lawfully provide an emergency supply of a controlled drug at the request of a patient or to dispense a prescription for a controlled drug that failed to exactly adhere to the handwriting requirements as set out in law. A preliminary analysis of the findings from the ongoing follow-up study indicate that community pharmacists continue to describe the negative effects of the restrictions of the Misuse of Drugs Regulations and their enforcement by the PSI on their ability to provide optimal patient care, with one pharmacist commenting that “*the restrictions of emergency supply under the Misuse of Drugs Act, and the repercussions under the Pharmacy Act, can hinder what I believe is required to provide optimal care for the patient*”.⁵¹ The COVID-19 related changes to both the Misuse of Drugs Regulations and the Medicinal Products Regulations address these concerns with the provision to provide up to 5 days’ supply of a controlled drug in an emergency to a patient at their request and the authority for practitioners to issue prescriptions for controlled drugs electronically that do not have to comply with handwriting requirements. Based on the findings of Lynch & Kodate and the preliminary findings of the follow-up study, it is unlikely that pharmacists would advocate a return to the more restrictive requirements for the supply of a controlled drug that pertained prior to the advent of the COVID-19 emergency.^{48,51}

A notable feature of the newly introduced Regulations is their reliance on the pharmacist applying their expert professional opinion when implementing them. The various provisions which allow for prescriptions to be repeated on an extended number of occasions and for pharmacists to provide emergency supplies of medicines at the request of the patient are subject to the pharmacist’s professional opinion and them determining that the supply is safe, necessary and appropriate for the continued treatment of their patient. This overt acknowledgement of the competency of the pharmacist to appropriately apply their professional discretion to act in the best interests of their patients, thereby extending their scope of practice, is significant. Lynch & Kodate reported that many pharmacists considered that 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 in the best interests of their patients.⁴⁸ Preliminary findings of the follow-up study indicate that the perceived absence of

trust in their professional competence to act appropriately in the best interests of their patient remains a concern for community pharmacists with one respondent noting “I believe in regulation, but I feel that I’m being infantilized by my regulator. After 30 years practice, I believe I should have a little bit more scope, than currently when acting in my professional capacity” while another commented “I have always felt that the PSI distrusts pharmacists and feels its role is to protect the public from us”.⁵¹ Pharmacists in practice are very likely on this basis to welcome the explicit acknowledgement of their expertise and competence contained in the amendment Regulations to act professionally and apply their discretion when implementing their various provisions in the best interests of their patients. They will be concerned if such acknowledgement only pertains for the duration of the COVID-19 emergency and is revoked subsequently.

Conclusion

In response to the emerging public health emergency related to COVID-19, Ireland introduced key regulatory changes across a range of areas including those relating to the registration of healthcare professionals and the supply of medicines including controlled drugs. These regulatory changes, in addition to fulfilling key principles of “better regulation” such as necessity and agility, have addressed concerns that pharmacists previously identified as limiting their professional practice and their ability to adequately meet the pharmaceutical needs of their patients. While further regulatory changes are required such as in the area of e-prescribing, it is important that regulatory changes which acknowledge the professional competency of the pharmacist and their capacity to effectively discharge their professional discretion as appropriate in the interests of their patients, are retained and further extended so as to maximize their contribution to the delivery of healthcare and improving patient outcomes.

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References

- Erku DA, Belachew SA, et al. hen fear and misinformation go viral: Pharmacists’ role in deterring medication misinformation during the ‘infodemic’ surrounding COVID-19 [published online ahead of print, 2020 May 1]. *Res Soc Adm Pharm.* 2020 <https://doi.org/10.1016/j.sapharm.2020.04.032>. S1551-7411(20)30455-1
- Eysenbach G. How to Fight an infodemic: The Four Pillars of infodemic management. *J Med Internet Res.* 2020 Jun 29;22(6), e21820.
- O’Brien M, Moore K, McNicholas F. Social media Spread during covid-19: the Pros and Cons of Likes and shares. *Ir Med J.* 2020 03;113(4):52.
- The Lancet Infectious Diseases. The COVID-19 infodemic. *Lancet Infect Dis;* 2020 [Epub ahead of print] [https://doi.org/10.1016/S1473-3099\(20\)30565-X](https://doi.org/10.1016/S1473-3099(20)30565-X).
- Health Services Executive (Ireland). *Acute Hospitals Drugs Management Programme - COVID-19 Guidelines*; 2020. Available from: <https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme/acute-hospitals-drugs-management-programme.html>.
- National Centre for Medicines Information. *Therapeutics Today: Information on COVID-19*; 2020. Available from: <http://www.stjames.ie/GPsHealthcareProfessionals/Newsletters/TherapeuticsToday/Therapeutics%20Today%20April%202020.pdf>. Accessed July 27, 2020.
- Pope C. *Coronavirus: Pharmacists Say Supplies Solid as ‘panic Buying’ Dies Down.* The Irish Times; 2020. Available from: <https://www.irishtimes.com/news/ireland/irish-news/coronavirus-pharmacists-say-supplies-solid-as-panic-buying-dies-down-1.4208250>.
- WHO. *Coronavirus Disease (COVID-19) Advice for the Public: Mythbusters.* World Health Organisation; 2020. Available from: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters>.
- Alexander M, Jupp J, Chazan G, O’Connor S, Chan A. Global oncology pharmacy response to COVID-19 pandemic: Medication access and safety. *J Oncol Pharm Pract.* 2020 Jul;26(5):1225–1229.
- Al-Quteimat OM, Amer AM. The impact of the COVID-19 pandemic on cancer patients. *Am J Clin Oncol.* 2020 Jun;43(6):452–455.
- Cabañas MJ, Queralt Gorgas M. The pharmacist facing the logistics of safely dispensing, storing and preserving drugs in healthcare units. *Farm Hosp.* 2020 13;44(7):53–56.
- Gil-Navarro MV. La farmacia hospitalaria en el equipo multidisciplinar de las unidades COVID de hospitalización. *Farm Hosp.* 2020 Jun 12;(7):40–42.
- McConachie S, Martirosov D, Wang B, Desai N, Jarjosa S, Hsaiy L. Surviving the surge: evaluation of early impact of COVID-19 on inpatient pharmacy services at a community teaching hospital. *Am J Health Syst Pharm.* 2020. <https://doi.org/10.1093/ajhp/zxaa189> [Epub ahead of print].
- Slimano F, Baudouin A, Zerbit J, et al. *Cancer, immune suppression and coronavirus disease-19 (COVID-19): need to manage drug safety (French society for oncology pharmacy [SFPO] guidelines)*88. *Cancer Treat Rev.*; 2020 Aug:102063.
- International Pharmaceutical Federation (FIP Health Advisory). *Coronavirus SARS-CoV-2/COVID-19 Pandemic: Information and Guidelines for Pharmacists and the Pharmacy Workforce Covid-19: Guidelines for Pharmacists and the Pharmacy Workforce.* The Netherlands. 2020. Available from: <https://www.fip.org/files/content/priority-areas/coronavirus/Coronavirus-guidance-update-ENGLISH.pdf>.
- Koster ES, Philbert D, Bouvy ML. Impact of the COVID-19 epidemic on the provision of pharmaceutical care in community pharmacies. *Res Soc Adm Pharm.* 2020. <https://doi.org/10.1016/j.sapharm.2020.07.008> ([Epub ahead of print]).
- Li M, Razaki H, Mui V, Rao P, Brocovich S. The pivotal role of pharmacists during the 2019 coronavirus pandemic [published online ahead of print, 2020 Jun 1] *J Am Pharm Assoc.* 2020. <https://doi.org/10.1016/j.japh.2020.05.017>. S1544-3191(20)30260-0.
- Merchan C, Soliman J, Ahuja T, et al. COVID-19 pandemic preparedness: A practical guide from an operational pharmacy perspective. *Am J Health Syst Pharm.* 2020. <https://doi.org/10.1093/ajhp/zxaa212> ([Epub ahead of print]).
- Nguy J, Hitchen SA, Hort AL, Huynh C, Rawlins MDM. The role of a Coronavirus disease 2019 pharmacist: an Australian perspective [published online ahead of print, 2020 May 30] *Int J Clin Pharm.* 2020:1–6. <https://doi.org/10.1007/s11096-020-01067-4> [Epub ahead of print].
- Zheng SQ, Yang L, Zhou PX, Li HB, Liu F, Zhao RS. ecommendations and guidance for providing pharmaceutical care services during COVID-19 pandemic: A China perspective [published online ahead of print, 2020 Mar 26] *Res Soc Adm Pharm.* 2020. <https://doi.org/10.1016/j.sapharm.2020.03.012>. S1551-7411(20)30284-9.
- Cadogan CA, Hughes CM. On the frontline against COVID-19: Community pharmacists’ contribution during a public health crisis [published online ahead of print, 2020 Mar 31] *Res Soc Adm Pharm.* 2020. <https://doi.org/10.1016/j.sapharm.2020.03.015>. S1551-7411(20)30292-8.
- Hoti K, Jakupi A, Hetemi D, Raka D, Hughes J, Desselle S. Provision of community pharmacy services during COVID-19 pandemic: a cross sectional study of community pharmacists’ experiences with preventative measures and sources of information [published online ahead of print, 2020 Jun 11] *Int J Clin Pharm.* 2020: 1–10 <https://doi.org/10.1007/s11096-020-01078-1> [Epub ahead of print].
- Elbeddini A, Yeats A. Pharmacist intervention amid the coronavirus disease 2019 (COVID-19) pandemic: from direct patient care to telemedicine. *J Pharm Policy Pract.* 2020 Dec;13(1):23.
- Hollander JE, Carr BG. Virtually Perfect? Telemedicine for covid-19. *N Engl J Med.* 2020 Apr 30;382(18):1679–1681.
- Laato S, Islam AKMN, Islam MN, Whelan E. What drives unverified information sharing and cyberchondria during the COVID-19 pandemic? *Eur J Inf Syst.* 2020 May 3;29(3):288–305.
- Margusino-Framiñán Luis. Atención farmacéutica al paciente externo durante la pandemia COVID-19. *Telefarmacia. Farm Hosp.* 2020 Jun 12;(7):61–65.
- Tortajada-Goitia B. Encuesta de situación de la telefarmacia aplicada a la atención farmacéutica a pacientes externos de los servicios de farmacia hospitalaria en España durante la pandemia por la COVID-19. *Farm Hosp.* 2020 Jul 1;(4):135–140.
- Whitelaw S, Mamas MA, Topol E, Van Spall HGC. Applications of digital technology in COVID-19 pandemic planning and response. *Lancet Digit Health.* 2020;2(8): e435–e440. [https://doi.org/10.1016/S2589-7500\(20\)30142-4](https://doi.org/10.1016/S2589-7500(20)30142-4) ([Epub ahead of print]).
- Yemm KE, Arnall JR, Cowgill NA. Necessity of pharmacist-driven nonprescription telehealth consult services in the era of COVID-19. *Am J Health Syst Pharm.* 2020 Jun 23;77(15):1188, 1188.
- Ma C. Panic or Panacea, changing the pharmacist’s role in pandemic. *Soc Welfare.* 2020;79(7):2.
- Government of Ireland. *Pharmacy Act 2007.* Dublin: Government Publications Office; 2007. Available from: <http://www.irishstatutebook.ie/eli/2007/act/20/enacted/en/html>.
- Government of Ireland. *Emergency Measures in the Public Interest (Covid-19) Act 2020.* Dublin: Government Publications Office; 2020. Available from: <http://www.irishstatutebook.ie/eli/2020/act/2>.
- Government of Ireland. *Medicinal Products (Prescription and Control of Supply) Regulations 1993.* Office of the Attorney General; 2003. Available from: <http://www.irishstatutebook.ie/eli/2003/si/540>.
- Government of Ireland. *Misuse of Drugs Regulations 2017.* Dublin: Government Publications Office; 2017. Available from: <http://www.irishstatutebook.ie/eli/2017/si/173/>.
- Government of Ireland. *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020.* Dublin: Government Publications Office; 2020. Available from: <http://www.irishstatutebook.ie/eli/2020/si/98/made/en/pdf>.

36. Government of Ireland. *Misuse of Drugs (Amendment) Regulations 2020*. Dublin: Government Publications Office; 2020. Available from: <http://www.irishstatutebook.ie/eli/2020/si/99/made/en/pdf>.
37. PSI - The Pharmacy Regulatory, Irish Medical Council, Health Service Executive. *Guidance for Prescribers and Pharmacists on Legislation Changes to Facilitate the Safe Supply of Medicines during the COVID-19 Pandemic*. 2020. Available from: http://www.thepsi.ie/Libraries/COVID/Guidance_for_prescribers_and_pharmacists_on_legislation_changes_to_facilitate_the_safe_supply_of_medicines_during_the_COVID-19_pandemic.sfb.ashx.
38. Health Services Executive (Ireland). Be on call for Ireland. HSE.ie. Available from <https://www.hse.ie/eng/services/news/newsfeatures/covid19-updates/oncall/be-on-call-for-ireland.html>; 2020.
39. McGee H. *Over 600 Recruits 'Job Ready' for Be on Call for Ireland*. The Irish Times; 2020 May 7. Available from: <https://www.irishtimes.com/news/politics/over-600-recruits-job-ready-for-be-on-call-for-ireland-1.4247652>.
40. Merks P, Jakubowska M, Drelich E, et al. *The legal extension of the role of pharmacists in light of the COVID-19 global pandemic*. Res Soc Adm Pharm; 2020. <https://doi.org/10.1016/j.sapharm.2020.05.033> [Epub ahead of print].
41. Department of Health, Ireland. *eHealth Strategy for Ireland*. Department of Health; 2013. Available from: <https://assets.gov.ie/16174/092e7c62f97b472b83cdb6dfdcdfd5c7.pdf>.
42. Health Information and Quality Authority. *ePrescribing: An International Review*. HIQA; 2018. Available from: <https://www.hiqa.ie/sites/default/files/2018-05/ePrescribing-An-Intl-Review.pdf>.
43. Government of the UK. *The Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of Controlled Drugs during a Pandemic etc.) Regulations*. Queen's Printer of Acts of Parliament. 2020. Available from: <https://www.legislation.gov.uk/uksi/2020/468/>.
44. Executive of Northern Ireland. *The Misuse of Drugs (Amendment) Regulations (Northern Ireland) Executive of Northern Ireland*; 2020. Available from: <https://www.legislation.gov.uk/nisr/2020/73/regulation/1>.
45. Cochran G, Bruneau J, Cox N, Gordon AJ. Medication treatment for opioid use disorder and community pharmacy: Expanding care during a national epidemic and global pandemic. *Subst Abuse*. 2020 Jul 2;41(3):269–274.
46. Green TC, Bratberg J, Finnell DS. Opioid use disorder and the COVID 19 pandemic: a call to sustain regulatory easements and further expand access to treatment. *Subst Abuse*. 2020 Apr 2;41(2):147–149.
47. Darragh O'Loughlin. *Covid-19 Crisis Provides a Chance to Improve Patient Outcomes*. The Irish Examiner; 2020 Jul 14. Available from: <https://www.irishexaminer.com/opinion/columnists/arid-40015370.html>.
48. Lynch M, Kodate N. Professional practice following regulatory change: an evaluation using principles of "Better Regulation". *Res Soc Adm Pharm*. 2020 Feb;16(2):208–215.
49. Department of the Taoiseach, Ireland. *Regulating Better A Government White Paper Setting Out Six Principles of Better Regulation*; 2004 Jan. Available from: <https://assets.gov.ie/3477/281118144439-cf60aac3e3504e6f9f62f0ccda38f203.pdf>.
50. Professional Standards Authority, UK. *Right Touch Regulation (revised) 2015*. Available from: <https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf>.
51. Lynch M, Kodate N, O'Leary A. *Ethical approval: the Pharmacy Act: 'Is it a model of better regulation?'. A Follow-Up Study of Community Pharmacists' Experiences of the Regulation of Pharmacy in Ireland*. Royal College of Surgeons in Ireland REC201908007; 2019.