

GUIDE TO CANCELLING YOUR PHARMACY REGISTRATION

to facilitate compliance with Section 59 of the Pharmacy Act 2007 and Rule 7 of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008)

Introduction

When the owner of a retail pharmacy business (pharmacy) closes or proposes to close a pharmacy, it is in the best interests of the pharmacy owner, all relevant pharmacists, patients and the public that the appropriate procedures are followed.

It is essential that the PSI is notified that the pharmacy intends to close and that an application for the cancellation of the registration of the pharmacy concerned is made to the Registrar of the PSI¹. The registration of a pharmacy cannot be cancelled until the application has been satisfactorily processed.

The absence of such a notification and cancellation, in the circumstances of the closure of a pharmacy, will continue to bind the owner in respect of his or her responsibilities as such an owner under the Act (including the payment of fees, etc.), for so long as the registration of the pharmacy concerned remains in place.

¹ There is a form available to apply for the cancellation of the registration of a retail pharmacy business. This form is attached as an appendix to these guidelines. Alternatively, the form may be downloaded from the PSI website (www.PSI.ie) or may be obtained from the Retail Pharmacy Business section of the Inspection and Enforcement Unit of the PSI. This form sets out certain arrangements that the pharmacy owner must put in place in under Rule 7 of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008). An application for cancellation of the registration of a pharmacy should be made by post to The Registrar, Pharmaceutical Society of Ireland, PSI House, Fenian Street, Dublin 2.

Rule 7 of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008) states:

Cancellation of Registration

“7. An application for the cancellation of the registration of a retail pharmacy business under Section 59 of the Pharmacy Act shall be made by the pharmacy owner in writing to the Registrar setting out the arrangements made, or to be made, in respect of -

- (a) the disposal of medicinal products held at that pharmacy, and*
 - (b) the records of the dispensing or supply of medicinal products conducted at that pharmacy, having regard for the reasonable needs of patients to continue to have access to such records,*
- and shall be accompanied by any fee which may be payable in connection with that application.”*

The Pharmacy Act 2007 and the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008), can be accessed via the PSI website.

Furthermore, the absence of the required notification of cancellation of a pharmacy's registration may have consequences for any pharmacist who held a position of responsibility in the pharmacy in the period leading up to its closure. Any such pharmacist must ensure that arrangements are in place to facilitate the continuity of patients' care, in accordance with their obligations under the statutory Code of Conduct for pharmacists. Superintendent pharmacists, supervising pharmacists and pharmacy owners must also ensure that medicines are disposed of and records managed appropriately.

The superintendent and supervising pharmacist for the pharmacy must be facilitated in complying with their professional and other responsibilities.

Facilitating Patients' Access to Records and Continuing Care

In view of the important role that the pharmacy has played in the local community, perhaps over many years, and in the continuing interests of the patients and the public that the pharmacy has served:

- Patients and the public should be notified of the proposed closure as early in the process of planning the closure as possible. For *planned* closures this should occur where possible at least twelve weeks, and certainly no later than four weeks, before the actual closure. For *unplanned* closures, where exceptional circumstances apply, a shorter timeframe may be deemed acceptable following consultation with the PSI and, if appropriate, other relevant bodies;
- Public notices which inform both patients and members of the public that the pharmacy is closing should be displayed in the pharmacy, including externally visible notices, for example, in pharmacy windows. The use of public notices in the local media, as well as in other local healthcare facilities may also be appropriate. Any notices should, at a minimum, include the date the pharmacy will be closing, details of where patients can get information on other pharmacies in the local area, details of the systems in place to manage pharmacy records and details of the relevant pharmacist(s) with whom patients can discuss any issues relating to patient records or their continuing care, e.g. the obtaining of consent for the transfer of such records to another pharmacy;
- Local prescribers and other healthcare professionals should be informed of the pharmacy closure and provided with the contact details of the person or persons holding the prescription and other records;
- Adequate notice of the proposed closure is essential so that patients may make alternative arrangements in respect of any health information or records that have been held in the pharmacy and arrange for another pharmacy to continue their care. Superintendent and supervising pharmacists should, therefore, ensure relevant patients are contacted to alert them to the proposed closure. Patients who wish to obtain their prescriptions, or copies thereof, and other records held in the pharmacy that may be necessary for their continuing care and wellbeing should be facilitated. To accommodate patients who are unable to attend at the pharmacy to collect their prescriptions various options, such as returning the current prescription to the relevant prescriber for collection there or posting prescriptions which have not been fully dispensed to patients, should be considered;

- Patients and the public should be informed of where they can access information on pharmacies in the locality. Details of all registered pharmacies can be accessed via the register of retail pharmacy businesses on the PSI website (www.PSI.ie) and via the Health Atlas on the HSE website (www.hse.ie);
- Particular consideration should be given to the arrangements for ensuring that the most vulnerable patients, including those with particularly complex therapeutic or pharmaceutical care needs, are facilitated in identifying an alternative source of medication supply and continuing care. Inter-professional liaison with the new service provider, including agreement on care transfer protocols, may be required for such patients to ensure that all necessary patient records and clinical information are transferred appropriately in the interests of continuing care for patients;
- Where the pharmacy is putting a system in place that would involve the transfer of patient records, such as prescriptions, to another pharmacy patient consent for these arrangements should, where practicable, be sought and given. Therefore, superintendent and supervising pharmacists should ensure all relevant patients are identified and contacted. The contact details of the pharmacy to which records will be transferred should be conveyed to the patients and, in cases where patients may wish to choose an alternative pharmacy their wish should be facilitated;
- Adequate and appropriate arrangements should be put in place in order to assure patients (and the public) that any records relating to them that were held in the pharmacy will remain confidential and under appropriate professional control and, insofar as practicable, that they will be kept in a manner whereby future access will be available to them should the need arise. It is the responsibility of the owner and superintendent pharmacist to ensure all patient records are maintained as outlined, that an appropriate custodian of these records is appointed and the custodian's contact details are communicated to patients;
- Prescription and other records normally held in a pharmacy are covered by the provisions of the Data Protection Acts 1988 and 2003 and related legislation. It is, therefore, important to ensure that the requirements of this legislation are complied with when handling patient records, following the closure of a pharmacy. Any custodian of such records is expected to be aware of their obligations under these Acts, in relation to the secure storage and eventual disposal of such records, and to act accordingly;
- Pharmacy owners and superintendent pharmacists must also adhere to all other relevant record-keeping requirements post pharmacy closure, including those set out in the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), the Medicinal Products (Prescription and Control of supply) Regulations 2003 (S.I. No. 540 of 2003)(as amended), the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended), the European Communities (Animal Remedies)(No.2) Regulations 2007 (S.I. No. 786 of 2007) (as amended). The pharmacy owner and superintendent pharmacist may consider it appropriate to retain records beyond the legally required retention period, as such records may be required for legal, insurance or other purposes at some time in the future. All electronic records should also be accessible for an appropriate timeframe following the closure of the pharmacy.

Disposal of Medicinal Products

- The disposal of medicinal products, including veterinary medicinal products and non-prescription medicinal products, must be carried out in a manner that will not result in any danger to public health or risk to the environment, in accordance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008²;
- It is also essential that the PSI's *Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business* and all legislative requirements that are applicable to waste medicinal products, primarily the Waste Management Act 1996 (as amended) and related legislation, are complied with when disposing of medicinal products;
- Where medicinal product stock is of merchandisable quality, it may be appropriate to contact the original supplier regarding their return. If medicinal products are being returned to the supplier, the integrity of the products must be assured by the availability of a satisfactory audit trail, including the relevant invoices;
- Medicinal products that are not of merchandisable quality, such as expired medicines, patient-returned medicines, medicines that are in the form of broken bulk, medicines which do not have a batch number or an expiry date, medicines which have been stored outside the terms of their marketing authorisation or medicines which are otherwise non-conforming, should be disposed of in accordance with the PSI's *Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business*;
- Any scheduled poisons or other chemicals held at the pharmacy should also be disposed of in a manner that will not result in any danger to public health or risk to the environment;
- The destruction and disposal of controlled drugs should be carried out in accordance with the PSI's *Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business*. The destruction of Schedule 2 controlled drugs must be witnessed in compliance with the requirements of Regulation 22 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended), and the controlled drugs register retained (for the period of 2 years from the date of the final destruction entry) by the owner of the pharmacy or the appointed custodian of such records.

Removal of Signs and Public Descriptions

- Signs and public descriptions relating to the pharmacy should be removed at the time the pharmacy closes. This includes all signs which contain the words pharmacy, chemist, pharmacist or any related words;
- The certificate of registration of the retail pharmacy business should be removed following the closure of the pharmacy and must be returned to the PSI within 14 days of the cancellation of the pharmacy's registration.

² To otherwise dispose of such products is designated as an offence under the Pharmacy Act 2007.

- Additional written materials which refer to the pharmacy, including stationary, invoices, receipts, bags and any related items, should be removed or discontinued when the pharmacy closes.

Summary

In order to fully process an application for the cancellation of the registration of a retail pharmacy business, all of the pharmacy's medicinal products, scheduled poisons and other chemicals must have been appropriately disposed of, or alternatively processed, and no such products should remain on the premises. Additionally, all patients should have been facilitated to ensure they have continuing access to their records, through an appropriate custodian.

The pharmacy owner and all relevant pharmacists should be cognisant of patients' continuing care needs, throughout the process of closing a pharmacy.

Note: Pharmacy owners, superintendent and supervising pharmacists who are in the process of cancelling the registration of a retail pharmacy business can contact the PSI if further information, advice or assistance is required.

References

- a) Pharmacy Act 2007
- b) Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)
- c) Code of Conduct for pharmacists
- d) Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008)
- e) PSI Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business. May 2011
- f) Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003 (as amended))
- g) European Communities (Animal Remedies) (No. 2.) Regulations 2007 (S.I. No. 786 of 2007) (as amended)
- h) Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended)
- i) Waste Management Act 1996 (as amended)
- j) Data Protection Acts 1988 and 2003

All legislation can be accessed via www.irishstatutebook.ie. Medicines legislation and PSI Guidelines can be accessed via the PSI website www.PSI.ie. Data Protection legislation can be accessed via www.dataprotection.ie.