Guidance for Pharmacists on the Safe Supply and Administration of Prescription-Only Medicines for the Purpose of Saving Life or Reducing Severe Distress in an Emergency

Pharmaceutical Society of Ireland

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Contents

1. Background

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 (S.I. 449/2015) came into effect on 15 October 2015. These amending Regulations make the following changes to the availability of certain prescription-only medicines:

1. The Regulations increase access to specified prescription-only medicines in an emergency situation. The specified medicines are adrenaline, naloxone, glyceryl trinitrate, salbutamol and glucagon. The Regulations permit:

- the supply and administration of these prescription-only medicines, without a prescription, by trained non-medical persons, to a person in an emergency[1],

- the supply and administration of these prescription-only medicines, without a prescription, by trained pharmacists, to a person in an emergency, even when the particular medicine has not been previously prescribed for the person requiring it.

2. The Regulations also permit trained pharmacists to supply and administer two additional vaccines, namely Pneumococcal and Herpes Zoster Vaccine, in the course of his or her professional practice, in accordance with the Immunisation Guidelines for Ireland[2]. Guidance for pharmacists on the supply and administration of these vaccines will be issued separately.

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 can be accessed in full at www.irishstatutebook.ie.

2. About this Guidance

The purpose of this guidance is to facilitate pharmacists and pharmacy owners, in meeting the legal requirements for supply and administration of specified prescription-only medicines to a person in an emergency.

This guidance does not provide information on recognising or treating emergency conditions, or clinical advice on the prescription-only medicines that can be supplied in an emergency. This information will be dealt with in detail in PSI approved training that pharmacists must complete in order to supply and administer medicines under these Regulations.

Guidance for pharmacists on the supply of emergency medicines for use by trained non-medical persons will be issued separately.

1 'Emergency' for the purposes of Regulations 4C, 4D, 4E and 20(10) and (11) means a situation in which the physical state of an individual reasonably leads another to suspect that the first individual is experiencing a life-threatening event that requires the provision of immediate care to assist the physiological functioning of that person.

2 The Immunisation Guidelines for Ireland are published and updated by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland, and are available to view at www.hse.ie.

3. Introduction

The enactment of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 increases access to certain prescription-only medicines in an emergency situation. This has the potential to save the life of a person who otherwise may not have access to the appropriate treatment within the necessary time frame.

A pharmacist is authorised to supply and administer specified prescription-only medicines in the course of their professional practice, without a prescription (even if the person has not been prescribed the medicine before), at any place, for the purpose of saving life or reducing severe distress in an emergency, provided that they comply with the requirements of the Regulations. In order to supply and administer the prescription-only medicines specified under these Regulations the pharmacist must first successfully complete a training course approved by the PSI, on the safe use of that medicine, and obtain the prescribed certificate.

3.1 Explanation of 'Emergency' in these Regulations

The introduction of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015, increases access to medicines in an emergency. 'Emergency' in this context is defined in the Regulations as:

'Emergency', for the purposes of Regulations 4C, 4D, 4E, and 20(10) and (11), means a situation in which the physical state of an individual reasonably leads another to suspect that the first individual is experiencing a life-threatening event that requires the provision of immediate care to assist the physiological functioning of that person.

These Regulations authorise a pharmacist, who has successfully completed approved training, to supply a person with, and to administer to the person, specified prescription-only medicines in an emergency:

- without a prescription or authorisation from a registered medical practitioner, dentist or nurse,
- even if the treatment has not been prescribed for the patient on a previous occasion,
- at any place i.e. within or outside the pharmacy (provided it is in the course of their professional practice).

Note: Under the new Regulations the pharmacist can supply and administer one of the specified prescription-only medicines to a person if it is an emergency as defined above, i.e. the person is 'experiencing a life-threatening event that requires the provision of immediate care'. This legislation does not affect or amend the provisions of Regulation 8, Exemptions for Emergency Supply, of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended[3].

3 Information on the requirements for an emergency supply of a prescription-only medicine under Regulation 8 of the Medicinal Products (Prescription and Control of Supply) Regulations, 2003, as amended, can be found in the PSI's 'Guidelines on the Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business'.

4. Guidance

4.1 Medicines that a Pharmacist Can Supply a Person with, and Administer to a Person, in an Emergency

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 amends the Eighth Schedule of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended. This Schedule details the medicines that may be supplied and administered by a pharmacist pursuant to Regulation 4B of these Regulations, along with the route of administration, indication for which the medicine may be administered, and the dosage and conditions of administration. According to the Schedule, the prescription-only medicines that may be supplied and administered by a pharmacist in an emergency are set out in the table below.

Note: There are a number of vaccines also listed in this Schedule. Guidance for pharmacists on the supply and administration of these vaccines will be issued separately.

Medicine	Route of administration	Indication for which the medicine may be administered	Dosage and conditions of administration
Epinephrine (adrenaline) injection, presented as a pre-filled syringe or ampoule[4]	Intramuscular or subcutaneous injection	Adults and children: For the emergency treatment of anaphylactic shock	In accordance with the summary of product characteristics of the product administered and relevant national guidelines
Glucagon hydrochloride for injection	Intramuscular or subcutaneous injection	Adults and children: For the emergency treatment of hypoglycaemia	In accordance with the summary of product characteristics of the product administered
Glyceryl trinitrate sublingual spray	Sublingual spray	Adults: For the emergency treatment of severe angina attack	In accordance with the summary of product characteristics of the product administered
Naloxone hydrochloride 1mg/ml pre-filled injection	Intramuscular injection	Adults and children: Respiratory depression secondary to known or suspected narcotic overdose	In accordance with the summary of product characteristics of the product administered and relevant national guidelines
Salbutamol 100mcg multi-dose inhaler	Oral inhalation	Adults and children: For the emergency treatment of acute asthmatic attack	In accordance with the summary of product characteristics of the product administered

4 Please note specific training is needed in order to administer adrenaline presented as an ampoule.

4.2 Role of the Superintendent Pharmacist

The superintendent pharmacist has overall responsibility and accountability for all medicines supplied and administered in the pharmacy or pharmacies which are under their control. The particular responsibilities of the superintendent pharmacist in relation to the provision of medicines in an emergency, would include ensuring that:

- all pharmacists providing this service have completed training which has been approved by the PSI and are the holders of the prescribed certificate(s) as evidence of that fact,
- all trained pharmacists are competent to supply and administer these medicines, and are familiar with how to use the devices available in the pharmacy,
- all trained pharmacists are familiar with the location of emergency medicines and relevant equipment in the pharmacies in which they practise and have undertaken practice runs of what to do in an emergency,
- appropriate professional indemnity arrangements are in place for the provision of this service,
- appropriate and robust policies and procedures are in place for the provision of this service and these policies and procedures are regularly reviewed and updated in accordance with best practice,
- all necessary equipment and facilities to provide this service are available on the pharmacy premises e.g. sharps bin, medicine waste bin with sealable lid,
- infection control measures are in place, including hand hygiene, and provision of appropriate personal protective equipment for staff e.g. disposable gloves. All pharmacists who have completed training, and all other pharmacy staff, as appropriate, should be offered vaccination against Hepatitis B. The receipt or refusal of the vaccination, and the completion of vaccination regimes, should be appropriately documented.

4.3 Pharmacist Training Requirements

Under the Regulations, in order to supply and administer specified prescription-only medicines to a person in an emergency the pharmacist must have completed a training course approved by the PSI and hold a valid certificate as evidence of that fact. Certificates and any other relevant records associated with the pharmacist's training should be retained in the pharmacy. The pharmacist should ensure that they refresh their knowledge and skills by regularly reviewing the training materials. It is recommended that the pharmacist periodically reads the relevant product's Package Leaflet and Summary of Product Characteristics (SmPC) to ensure that they remain confident in the administration of these medicines and are in a position to act quickly in an emergency situation. Pharmacists should ensure that they are competent at using all brands of the medicine available, as the method of administration often varies between brands. The more familiar the pharmacist is with the administration technique of these medicines, the more likely they are to remain calm when faced with an emergency, and to keep those around them calm.

All training and continued professional development should be documented.

4.4 Other Staff Training

Other staff members should be aware that the pharmacist can supply and administer certain prescription-only medicines in an emergency. Training should be provided to staff, so that they can recognise patient requests or symptoms that could indicate an emergency and are aware of the importance of alerting the pharmacist immediately. Staff members should also be trained on what to do in an emergency in order to assist the pharmacist in attending to the person as quickly as possible e.g. with regard to calling an ambulance and/or local doctor and the storage location of the emergency medicines and other equipment that may be needed.

4.5 Equipment and Facilities

Pharmacists should ensure that they have the appropriate equipment and facilities readily available in order to safely administer medicines in an emergency. For example, a spacer device, a sharps bin, a medicines waste bin with sealable lid, disposable gloves, alcohol gel. These should be stored in an area of the pharmacy that is easily accessible to the pharmacist or a trained member of staff in an emergency and all pharmacists should be familiar with the safe use and maintenance of such equipment.

4.6 Stock Management of Emergency Medicines

The general requirements for the management of the sourcing, storage and disposal of medicines as set out in the relevant PSI Guidelines[5,6,7] should be adhered to.

Pharmacists may wish to keep a stock of these medicines in a designated place in the dispensary which would be easily accessible in an emergency. Adequate stock of all medicines to be supplied and administered in an emergency should be maintained at the pharmacy providing the service.

It should be noted that the Naloxone 1mg/ml pre-filled injection product detailed in the Eighth Schedule is currently not an authorised product in Ireland. All exempt medicines must be sourced from an authorised wholesaler in Ireland or the EEA[8].

5 Guidelines on the Sourcing of Medicinal Products for Sale or Supply by a Retail Pharmacy Business

6 Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business

7 Guidelines on the Disposal of Medicinal Products for a Retail Pharmacy Business

8 Information on the appropriate sourcing of exempt medicines can be found in the PSI's 'Guidelines on the Sourcing of Medicinal Products for Sale or Supply by a Retail Pharmacy Business'.

4.7 Assessing the Patient and Obtaining Consent

Before administering any medicine, the pharmacist must fully assess the patient in line with their training to decide on what actions to take. The pharmacist should use their professional knowledge and training, and the policies and procedures in place in the pharmacy, to act in the best interest of the patient. If administering a medicine the pharmacist must be satisfied that they have the required competence to do so safely, and the potential benefit outweighs any risks. The pharmacist should be alert to any adverse reactions that may result from administration of one of these medicines and the consequences and likelihood of the person's condition worsening.

Where possible, the pharmacist must seek consent from the patient or their representative, such as a family member, friend or colleague before administering a medicine. If explicit consent cannot be obtained from the patient or their representative, the pharmacist must be satisfied that they have consent implied through the interaction with the person or the circumstances in which the medicine is to be administered.

In the unlikely event that the patient refuses treatment, the pharmacist should ensure the patient, or their representative, fully understands the risks of declining treatment. Emergency services should be called and/or the person referred to a doctor as appropriate. The pharmacist should document the refusal, any advice that they provided to the patient or their representative, and any other actions that were taken.

4.8 Follow-Up and Notifying the Person's General Practitioner

An ambulance should be called in all situations where a medicine needs to be administered to a person in an emergency, in order to carry out further assessment and ensure the person's condition is stable. The pharmacist should be available when the ambulance arrives to inform the paramedics about the medicine that they have administered and how they have managed the patient.

The Regulations require that a copy of the particulars recorded following the supply and administration of a prescription-only medicine in an emergency is forwarded to the person's General Practitioner (GP) (see record requirements detailed in section 5), unless the patient fails to provide the name and contact details of a GP. The relevant information must be forwarded to the GP, by electronic or other means, within seven days of the administration.

5. Supply and Administration Records

Adequate and appropriate records of the supply and administration of prescription-only medicines in an emergency must be kept. Any advice or follow-up provided should also be documented.

The Regulations require that the pharmacist, who administers the medicine, records the following particulars in a register kept for that purpose:

- date of administration,
- name, address, date of birth and sex of the person to whom the product was administered, (unless that person fails, or is unable, to provide such particulars),
- personal public service number (PPSN) of the person to whom the product was administered (unless that person fails to provide one),
- name, dosage, marketing authorisation number, batch number and expiry date of the product,
- their own name and PSI registration number,
- address of the pharmacy where the pharmacist carries on their professional practices,
- name, address and contact particulars of the person's GP (unless that person fails to provide this information),
- confirmation that prior to the administration of the product, consent was:

  a) obtained from the person to whom the product was administered, or

  b) if he or she was unable to give such consent—

  (i) obtained from his or her representative, such as a family member, friend or colleague, or

  (ii) implied through the interaction with the person to whom the product was administered, or the circumstances in which the product was administered.

The requirement for this information to be kept in a register shall be satisfied where this information is kept in the form of computerised records, if there is a printout for each day the pharmacy is open of the details recorded in the register. This printout must be certified (signed and dated) by the pharmacist who supplied and administered the medicine that the record is true and correct. This certification must be made within 24 hours after making the supply. To ensure that the pharmacy holds a complete history of medication supplied to a patient an electronic record of the supply and administration of any emergency medicine should, where this information is available, also be made in the Patient Medication Record (PMR) and included in the daily dispensing report for the pharmacy (this may also fulfil the record keeping requirements detailed above).

All records relating to the supply and administration of a prescription-only medicine in an emergency must be kept for at least two years, from the date of administration, at the pharmacy premises concerned and be available for inspection. Furthermore, the records must be preserved by the pharmacy owner for at least eight years from the date of administration. If the ownership of a pharmacy changes within that time period, the new owner will be responsible for preserving the records for the remainder of the designated time period.

6. Pharmacovigilance

As with all medicines, any suspected adverse reactions following supply of one of the specified prescription-only medicines in an emergency should be reported to the Health Products Regulatory Authority (HPRA), preferably online via the HPRA's website, www.hpra.ie. Reports should be as detailed as possible and include the medicine's batch number.

7. Patient Education

As well as being able to react and assist people in an emergency, pharmacists can improve patient and public safety by educating patients on the management of these conditions, through targeted counselling during the regular dispensing of these medicines. This may reduce the chance of such an emergency occurring, and may emphasize to the patient, the importance of carrying the correct medicine with them at all times, for use if an emergency does occur.

During the regular dispensing of these medicines to patients on foot of a prescription, the pharmacist should confirm the patient's understanding of their condition and provide information and resources to assist them. For example, it may be useful to counsel the patient on:

- how to use their medicine correctly, and the importance of regularly practising with a training device and familiarising themselves with the directions in the Package Leaflet,
- how to recognise the early signs and symptoms which may indicate that they are having an anaphylactic reaction, asthma attack, angina attack, hypoglycaemic attack, narcotic overdose, or other relevant emergency situation, as appropriate, so that where possible they can get help quickly and prepare to use their medicine if they have it with them,
- informing their friends and family about how to use the medicine and recognise early signs and symptoms, so that they too are prepared and can assist them if needed,
- the importance of carrying the medicine with them at all times,
- seeking urgent medical assistance if they have to use their medicine in one of these situations,
- how to avoid any known allergens or triggers,
- the importance of regularly checking the expiry date of their medicines, especially where they may not be using the medicine routinely,
- where they can get more information (for example from charities, patient support organisations or product websites).

Pharmacists should also highlight to patients and members of the public, that the pharmacy is a place they can go to get assistance and medicine in an emergency, if needed.

8. Policies and Procedures

Policies and Standard Operating Procedures (SOPs) must be in place, detailing all aspects of the supply and administration of medicines in an emergency. SOPs help to ensure that tasks and services are consistently carried out safely and effectively, in line with legislation and good practice. For activities that are not provided routinely, like the supply and administration of medicines in an emergency, it is particularly important to have documented procedures that all staff members are familiar with. The policies and procedures should clarify the process to be followed in the event of an emergency and should be specific to each pharmacy. The following key aspects should be included:

- patient requests and patient symptoms which would alert a staff member to call the pharmacist,
- when to call an ambulance,
- where the specified prescription-only medicines and equipment are stored in the pharmacy,
- obtaining consent from the patient or their representative (where possible),
- appropriate patient follow-up,
- disposal of sharps and used medicines,
- record keeping.

Having a clear procedure which all staff are familiar with, and regularly trained in, will help the pharmacist and their staff to remain calm and provide the best possible care to the patient in an emergency situation. The superintendent pharmacist and supervising pharmacist must be satisfied that all pharmacists practising in the pharmacy, and other relevant staff members, are trained on, and are following, the relevant and up-to-date policies and procedures pertaining to the safe supply and administration of medicines in these circumstances.

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9. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Have all pharmacists wishing to supply and administer emergency medicines under this legislation successfully completed the approved training?				
Does the pharmacist periodically review their training materials, the Package Leaflet and Summary of Product Characteristics (SmPC) of the relevant products to ensure that they remain competent to administer these medicines and are in a position to act quickly in an emergency situation?				
Are other staff members trained to alert the pharmacist if they see a patient in distress, and how to assist the pharmacist in an emergency?				
Is adequate stock of all medicines to be supplied and administered in an emergency, maintained at the pharmacy in a location that is easily accessible?				
Is there appropriate equipment and facilities readily available in order to safely administer medicines in an emergency?				
Is the pharmacist aware of what records need to be made following the administration of an emergency medicine?				
Is there a process in place to alert the patient's GP, where this information is provided, following administration of an emergency medicine?				
Is there appropriate professional indemnity arrangements in place for the provision of this service?				
During the regular dispensing of these medicines to patients on foot of a prescription, does the pharmacist confirm the patient's understanding of their condition and provide information and resources to assist them?				
Are there written policies and procedures in place for all aspects of the provision of this service?				
Are the policies and procedures regularly reviewed and updated in accordance with best practice?				
Is the superintendent and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the policies and procedures?				