Explanatory Note for Pharmacists, on the Supply of 'Emergency' Prescription-Only Medicines to a Listed Organisation

Pharmaceutical Society of Ireland

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Updates made following the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018 (S.I. 530/2018) are highlighted in grey.

Contents

1. Background

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 came into effect on 15 October 2015. These amending Regulations have made 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 in a listed organisation, 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 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, subject to the Immunisation Guidelines for Ireland[2]. To support and assist pharmacists in delivering a vaccination service the PSI has issued 'Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses' which is available at www.psi.ie.

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

2. About this Explanatory Note

The purpose of this explanatory note is to facilitate pharmacists and pharmacy owners in meeting the legal requirements for the supply of prescription-only medicines from a pharmacy to a listed organisation, for use in an emergency. This explanatory note outlines the various requirements to be fulfilled before a pharmacist can make such a supply.

Organisations which are entered onto the list of 'Listed Organisations' are able to procure the prescription-only medicines listed in Section 4.1, from a pharmacy, without a prescription. These medicines must be stored on the premises of the organisation and can only be used for supply and administration in an emergency. In order to supply or administer one of these medicines in an emergency, the person doing so must be engaged or employed by the listed organisation (including in a voluntary capacity) and they must have completed a training course approved by the Pre-Hospital Emergency Care Council (PHECC), or another body nominated by the Minister for that purpose.

The supply of prescription-only medicines to a listed organisation can only occur from a pharmacy, by or under the personal supervision of a pharmacist. Pharmacists have a legal and professional responsibility to ensure that these medicines are supplied with appropriate information to enable their correct use, and that the risk of them being used incorrectly or to cause harm is minimised.

The legal requirements for supply and administration of prescription-only medicines by a trained pharmacist in an emergency, is addressed in a separate guidance piece, the PSI's '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' which is available at www.psi.ie.

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. Useful Definitions

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 provides the following definitions:

'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.

'Listed organisation' means an organisation or emergency rescue organisation listed in the list of organisations maintained by the Health Products Regulatory Authority (HPRA) pursuant to Regulation 4D(3).

'Organisation' includes—

(a) an organisation, body, person or group in control of a place of worship, a place of hospitality, an entertainment venue, a place of work, a sports venue, a sports club, a train station, a bus station, a ferry port, an airport or aerodrome, a commercial aircraft, a passenger ferry, a supermarket, a shopping centre, an educational establishment, a childcare facility, a crèche, a museum, an art gallery, an exhibitions centre,

(b) An Garda Síochána,

(c) the Courts Service,

(d) a local authority,

(e) the Health Service Executive,

(f) a fire service,

(g) an emergency rescue organisation.

'Premises' includes any aircraft, hovercraft, ship, stall, land, building or vehicle.

For a description of the role and responsibilities of an 'Accountable Person' in a Listed Organisation see Section 4.3.

4. Guidance

4.1 Prescription-Only Medicines that can be Supplied to Listed Organisations for Use in an Emergency

The Medicinal Products (Prescription and Control of Supply) (Amendment) (No.2) Regulations 2015 introduces a Tenth Schedule to the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended. This Schedule details the medicines that may be supplied and administered by persons engaged or employed by Listed Organisations in emergencies pursuant to Regulation 4C of these Regulations, along with the route of administration and conditions of administration. The medicines that may be supplied from a pharmacy to a Listed Organisation[3] are:

- Epinephrine (adrenaline) auto-injector presented as a 300mcg pre-filled syringe
- Epinephrine (adrenaline) auto-injector presented as a 150mcg pre-filled syringe
- Glucagon hydrochloride for injection
- Glyceryl trinitrate sublingual spray
- Naloxone hydrochloride dihydrate 1mg/ml pre-filled injection
- Naloxone hydrochloride dihydrate 1.8mg nasal spray
- Salbutamol 100mcg multi-dose inhaler

3 As well as the emergency medicines listed in Section 4.1, 'Emergency Rescue Organisations' entered onto the list of Listed Organisations, can also procure a medical gas mixture consisting of 50% nitrous oxide and 50% oxygen, however this can only be procured from the holder of a wholesaler's authorisation.

4.2 Entry onto the List of Listed Organisations

In order for an organisation to procure stock for use in an emergency it must first notify the HPRA to be included in the list of Listed Organisations[4]. If an organisation wishes to procure stock for more than one premises[5] a notification must be made for each individual premises.

Where the HPRA is satisfied that the organisation has made a valid notification in accordance with the requirements of the Regulations they will enter the following details into the list of Listed Organisations, which will be published on the HPRA's website (www.hpra.ie):

a) name of the organisation, defined as the 'Listed Organisation',

b) address of the organisation that will procure the medicine(s),

c) the business name or trading style of the organisation, if different to the name referred to in (a),

d) medicine(s) which the organisation intends to procure,

e) address of the premises, which must not be a dwelling, where the medicine(s) will be stored,

f) name of the 'accountable person(s)' appointed by the listed organisation to ensure compliance with the Regulations.

Queries from organisations regarding the requirements to be entered onto the list of Listed Organisations should be referred to the HPRA.

4.3 Accountable Person in a Listed Organisation

A listed organisation must appoint one or more individuals, employed or engaged by the organisation (including in a voluntary capacity), as the accountable person[6]. The accountable person acts on behalf of the organisation to ensure compliance with the Regulations and must ensure that medicines are only procured from a registered pharmacy.

The accountable person must also:

- oversee and manage the appropriate storage of all medicines procured,
- oversee and manage the appropriate conditions for storage of all medicines procured,
- ensure that the medicines are only supplied to a person, or persons, (who may also be the accountable person) employed or engaged by the Listed Organisation, (including in a voluntary capacity) for supply and administration in an emergency,
- maintain confidential records at the premises of the Listed Organisation in relation to the procurement and storage of such medicines,
- ensure that the person(s) with responsibility for supplying and administering these medicines in an emergency has completed approved training, as detailed in the Regulations, and is in possession of a valid training certificate[7],
- assist An Garda Síochána or any other investigative body with its investigation in the event of an adverse event or incident relating to the procurement, storage, supply or administration of the medicine.

4 The Eleventh Schedule of the amending Regulations contains the particulars to be included in a notification for inclusion in the list of 'Listed Organisations'.

5 'Premises' includes any aircraft, hovercraft, ship, stall, land, building or vehicle.

6 The requirements regarding the appointment of an accountable person by listed organisations are contained in Regulation 4E of the amending Regulations.

7 Certificates are valid for a maximum period of 2 years from the date of issue.

4.4 Supplying Prescription-Only Medicines to a Listed Organisation

The pharmacist must be satisfied that any organisation requesting to procure prescription-only medicines is authorised to do so and is acting in accordance with the requirements of the Regulations. Prior to supply of a prescription-only medicine to a Listed Organisation a written order, signed by the accountable person, must be provided to the pharmacist. A person acting on behalf of the accountable person may present the signed order at the pharmacy, but the pharmacist must be satisfied that this person has the authority to do so. The signed order must contain the following particulars:

- name and address of the Listed Organisation,
- name of the accountable person appointed by the Listed Organisation to ensure compliance with the Regulations,
- permanent address at which the medicine will be stored, and supplied, if this differs from the address of the listed organisation,
- name, and except where it is apparent from the name, the pharmaceutical form and strength of the product,
- total quantity required.

The pharmacist must check the list of Listed Organisations on the HPRA website to confirm that the organisation, accountable person and medicines requested on the signed order have been notified to the HPRA, and all details are correct. Pharmacists can only supply prescription-only medicines that the Listed Organisation has notified to the HPRA for procurement, which are shown in the list of Listed Organisations. This will vary depending on the type of organisation making the request and the training that has been undertaken. The quantity of medicine that an organisation can obtain is not specified in the Regulations; pharmacists should use their professional judgement to ensure that appropriate quantities are supplied for the size and type of organisation making the procurement.

All prescription-only medicines supplied to Listed Organisations from a pharmacy must be authorised (i.e. licensed) for sale or supply in Ireland. The authorisation status of a product can be checked on the HPRA's website. All medicines should be supplied in the manufacturer's original pack and include the Package Leaflet (PL) which should be highlighted to the organisation procuring the medicine.

Following supply, the signed order must be kept for two years at the pharmacy premises concerned and be available for inspection.

4.5 Labelling a Product for Supply to a Listed Organisation

Labelling prescription-only medicines supplied from the pharmacy provides an important audit trail and enables the accountable person, or any trained non-medical person, employed or engaged by the listed organisation, to contact the pharmacy if they have a question or concern regarding the medicine. When affixing the label to the container or outer packaging of the manufacturer's original pack, important information should not be obscured, for example the expiry date and batch number of the product. The Regulations require that all products supplied to a listed organisation are labelled with:

- name of the organisation,
- name and address of the supplying pharmacy,
- date of supply,
- name of the product, being either the proprietary name or the non-proprietary name, with the name of the manufacturer or of the person responsible for placing the product on the market,
- the words 'Keep out of the reach of children',
- any cautionary and warning notices that the pharmacist, in the exercise of his/her professional judgement, deems appropriate[8].

4.6 Stock Management

The general requirements for the management of the sourcing, storage and disposal of medicines as set out in the relevant PSI Guidelines[9,10,11], should be adhered to.
As these products will be supplied to the listed organisation to keep as stock and will only be used in the event of an emergency, the pharmacist should endeavour to supply a product with a long expiry date, and highlight this date during supply so the accountable person knows when the product needs to be disposed of and/or replaced.

In the event that the medicine is used, expires or is no longer fit for purpose, pharmacists should ensure that the accountable person has appropriate information on the safe disposal of medicines. The accountable person should be facilitated and encouraged to return used, unwanted or expired medicines to the pharmacy for disposal, or advised of a local service in this regard. Pharmacists should inform the accountable person that it is not appropriate to dispose of waste medicines in standard household or commercial waste, and should provide advice regarding hazardous waste such as sharps.

8 As specified in the Fifth Schedule of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended.

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

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

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

4.7 Counselling

The pharmacist is professionally and legally responsible for the sale and supply of all medicines from the pharmacy. It is a key role of the pharmacist to ensure medicines are supplied with appropriate information for safe use and he/she should offer to demonstrate how to use the medicines. Where possible, obtaining a trainer device from the manufacturer of the product can help in this regard.

The accountable person is responsible for overseeing and managing the appropriate storage, including the storage conditions, of all emergency medicines held on the Listed Organisation's premises. To assist in meeting this requirement, the pharmacist should ensure that the accountable person has sufficient information with regard to the safe storage of the products as required by the product's Summary of Product Characteristics (SmPC). For example, advice regarding the correct temperature to store the product, to keep it away from direct sunlight/extremes of heat and to keep it out of the reach of children.

The pharmacist should provide sufficient information to the accountable person on all matters that they deem appropriate and offer to answer any questions that the accountable person may have. This may include information regarding:

- nature and use of the medicine,
- directions for use/how to administer the medicine, (including demonstration, if applicable),
- therapeutic effect which may be experienced from the use of the medicine,
- potential side effects that are likely to be experienced and how to deal with them,
- what to do if the medicine appears not to be working,
- storage of the medicine,
- other relevant information included in the product's SmPC,
- what to do with any previously dispensed medicine(s) no longer required (i.e. disposal of waste medicines).

4.8 Equipment for the Safe Use of Emergency Medicines

When supplying prescription-only medicines to a listed organisation, pharmacists should offer to supply, or advise where to obtain, any equipment that may be needed for their safe use, for example, a spacer device for use with a salbutamol inhaler (especially if the inhaler is being purchased by an organisation which caters for small children), a sharps bin, a medicines waste bin with sealable lid, disposable gloves, alcohol wipes, alcohol gel etc. The pharmacist should ensure that appropriate information is provided for the safe use and storage of this equipment.

5. Record Keeping

Adequate and appropriate records of the supply of prescription-only medicines to Listed Organisations must be kept. Any advice provided should also be documented.

The Regulations require that the pharmacist records the following particulars of the supply of a prescription-only medicine to a Listed Organisation in a register kept for this purpose:

- date of supply,
- name and address of the Listed Organisation,
- name of the accountable person appointed by the Listed Organisation to ensure compliance with the Regulations,
- permanent address at which the medicine will be stored and supplied, if this differs from the address of the Listed Organisation,
- name, and except where it is apparent from the name, the pharmaceutical form and strength of the product,
- marketing authorisation number, batch number and expiry date of the product,
- total quantity supplied,
- address of the pharmacy from which the supply is made.

The requirement for this information to be recorded in a register, shall be satisfied when kept in the form of computerised records, if there is a printout for each day the pharmacy is open of the details listed above, and this is certified (signed and dated) by a pharmacist that the record is true and correct. This certification must be made within 24 hours after making the printout. The daily dispensing/audit report for the pharmacy may fulfil these record keeping requirements where all the information listed above has been captured.

All records relating to the supply of prescription-only medicines to a listed organisation must be kept for two years at the pharmacy premises concerned and be available for inspection. 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. Policies and Procedures

Policies and Standard Operating Procedures (SOPs) must be in place detailing all aspects of the supply of prescription-only medicines to Listed Organisations. These should include the procedure to verify that the organisation and accountable person requesting the supply are entered in the list of Listed Organisations as well as the medicines being requested, the requirements for a signed order, any counselling that should be provided, and the particulars that need to be recorded. The superintendent pharmacist and supervising pharmacist must ensure 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 of medicines in these circumstances.

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1	April 2017
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7. 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
Does the pharmacist know what information must be contained on the signed order for supply of medicines to a listed organisation under this legislation?				
Does the pharmacist and relevant staff members, know to check the list of Listed Organisation's on the HPRA's website to confirm that the organisation and accountable person have been notified to the HPRA?				
Does the pharmacist know that only medicines that have been notified to the HPRA for procurement and are included with the organisation's name on the HPRA's list of Listed Organisations, can be supplied?				
Is the pharmacist aware of what information the product must be labelled with?				
Is the pharmacist able to provide appropriate counselling to assist in the safe storage and administration of the medicines supplied?				
Is the pharmacist aware of what records need to be made following the supply of a medicine to a listed organisation?				
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?				