

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

to Facilitate Compliance with Regulations 5(1)(g), 6, 8 and 11 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

Pharmaceutical Society of Ireland

Version 2 October 2017

Updates made following the enactment of the Misuse of Drugs Regulations 2017¹ (which replaced the Misuse of Drugs Regulations 1988 (as amended)² are highlighted in grey).

Contents

| | |
|---|----|
| 1. Introduction | 2 |
| 2. Legislative Basis | 2 |
| 3. Guidance | 2 |
| 3.1 Sourcing of Medicinal Products | 2 |
| 3.1.1 Sourcing from Authorised Manufacturers or Wholesalers | 3 |
| 3.1.2 Medicinal Products which should not be Sold or Supplied | 4 |
| 3.1.3 Inter-Pharmacy Exchange of Medicinal Products | 4 |
| 3.2 Medicinal Products which may be Sold or Supplied from a Pharmacy | 5 |
| 3.2.1 Marketing Authorisations | 6 |
| 3.2.2 Veterinary Medicinal Products | 7 |
| 3.2.3 Medicinal products Exempted from the Requirement to be Authorised | 7 |
| 3.3 Withdrawal or Recall of Medicinal Products from the Market | 8 |
| 3.4 Policies and Procedures | 9 |
| 3.5 Particular Care Settings | 9 |
| 4. Legislative References | 10 |
| 5. Self-assessment Checklist | 11 |

¹ Please note: where the Misuse of Drugs Regulations are cited in other legislation please refer to Schedule 9 'Provisions of revoked Misuse of Drugs Regulations 1988 and corresponding provisions in these Regulations' of the Misuse of Drugs Regulations 2017.

² Misuse of Drugs (Safe Custody) Regulations 1982, as amended, remain applicable.

1. Introduction

The purpose of these guidelines is to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the sourcing of medicinal products, including veterinary medicinal products, for sale or supply in conducting retail pharmacy businesses (pharmacies).

As pharmacies are the final link in the chain of supply of medicinal products from manufacturers to patients, all medicinal products sold and supplied through pharmacies must be sourced from appropriate manufacturers or wholesalers to assure the safety, quality and efficacy of such products. Compliance with the regulations and these guidelines is therefore essential if this objective is to be achieved and patient safety is to be maintained.

Every pharmacy should operate a comprehensive, auditable system for the sourcing and receipt of medicinal products.

2. Legislative Basis

The operation of a retail pharmacy business is governed by section 26(1) of the Pharmacy Act 2007, which requires every retail pharmacy business to be registered, and by the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which have been made by the Minister for Health and Children under Section 18 of the Pharmacy Act 2007, for the purposes of the health, safety and convenience of the public. Retail pharmacy business owners, superintendent pharmacists and supervising pharmacists are all required to conduct the retail pharmacy business in compliance with these provisions.

These guidelines have been prepared with a view to publication in accordance with regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) which provides that the PSI Council may publish detailed guidelines for the purpose of facilitating compliance with these Regulations. In that context, the guidelines are intended to facilitate better compliance with regulations 5(1)(g), 6, 8 and 11 insofar as those regulations relate to the sourcing of medicinal products for sale or supply through pharmacies.

3. Guidance

3.1 Sourcing of Medicinal Products

Regulation 6 sets out the requirements regarding the suppliers from whom pharmacies must obtain their medicinal products.

Regulation 6:

Sourcing of medicinal products

6.(1) *A person carrying on a retail pharmacy business shall obtain his or her supplies of medicinal products (including medicinal products on a general sales list) from persons—*

- (a) *who are themselves the holders of a manufacturer's authorisation or a wholesaler's authorisation in respect of such products, or*
- (b) *who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.*

(2) *A person carrying on a retail pharmacy business shall obtain his or her supplies of veterinary medicinal products from persons—*

- (a) *who are themselves the holders of a manufacturer's licence granted under Regulation 20 of the animal remedies regulations, or an animal remedies wholesaler's licence granted under Regulation 30 of those Regulations, in respect of such products, or*
- (b) *who are the holders of a licence granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.*
- (3)³ *Notwithstanding paragraphs (1) and (2), a person carrying on a retail pharmacy business may accept the return of a medicinal product, including a veterinary medicinal product, that had previously been dispensed or supplied, and such product shall be kept in a secure manner that is segregated from other medicinal products, including other such veterinary medicinal products, and shall be disposed of in a manner otherwise than for the purpose of use as a medicinal product or as a veterinary medicinal product.*
- (4) *The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient.*

3.1.1 Sourcing from Authorised Manufacturers or Wholesalers

A person carrying on a retail pharmacy business must only source medicinal products, including veterinary medicinal products and non-prescription medicinal products, from an authorised manufacturer or an authorised wholesaler. This is necessary in order to ensure the security and integrity of the supply chain, to assure the quality, safety and efficacy of the

medicinal product sourced and to maintain its traceability. Ensuring that medicinal products are only sourced from an authorised manufacturer or authorised wholesaler reduces the risk of counterfeit stock entering the medicinal product supply chain, thereby minimising any risk to patient health or safety.

A list of authorised manufacturers and authorised wholesalers from whom medicinal products are sourced should be maintained by each pharmacy. There should be a written procedure in place which outlines the steps to be taken to verify the authenticity of suppliers. It is important that these verification procedures are applied retrospectively for existing suppliers and are performed prior to sourcing medicinal products from new suppliers.

Lists of and information on all Irish authorised manufacturers and wholesalers are available on the Health Products Regulatory Authority (HPRA) website (www.hpra.ie). In reviewing the authority of a supplier to supply medicinal products, it is important to take into consideration the particular category of medicinal product involved. In relation to wholesale suppliers, the information available on the HPRA's website includes the particular categories of medicinal products that the wholesaler can supply.

The authorisation status of wholesalers and manufacturers based in other EU/EEA countries can be checked with the competent authority in the relevant country, e.g. the Medicines and Healthcare products Regulatory Agency (MHRA) in UK, etc. Where there is difficulty in checking this information with the competent authority in the relevant EEA country, clarification should be sought from the HPRA. It is the responsibility of the pharmacy owner, superintendent pharmacist and supervising pharmacist to ensure all medicinal products available for sale or supply in their pharmacy are authorised to be on the Irish market.

3 The segregation and disposal of patient-returned medicinal products is dealt with in greater detail in the PSI Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business.

Documentation should be available in the pharmacy which permits clear identification of the supplier of each consignment of medicinal products received by the pharmacy and of the medicinal products therein, e.g. supplier invoices⁴, delivery docket. Such documentation should be retained so as to ensure full traceability.

3.1.2 Medicinal Products which should not be Sold or Supplied

If a pharmacist or pharmacy owner suspect they are being offered a counterfeit, defective or inappropriately authorised medicinal product, the product should not be ordered and the supplier should be reported to the HPRA.

If a pharmacist or pharmacy owner suspect they have been supplied with a counterfeit, defective or inappropriately authorised medicinal product, the product should be segregated from legitimate pharmacy stock; it should be stored in a designated quarantine area of the pharmacy and clearly labelled, and must not be used for sale or supply pending review and clarification with the HPRA.

Medicinal products previously dispensed or supplied must never re-enter the supply chain. A pharmacy is not permitted to sell or supply a previously dispensed or supplied medicinal product, e.g. medication returned from a patient's home or from a residential care home. Such products should be stored in a designated area of the pharmacy, segregated from stock and labelled 'Medicines for Destruction', pending timely removal for disposal and destruction⁵.

Medicinal products which are medical samples should not be stocked in a pharmacy or dispensed or supplied through a pharmacy.

3.1.3 Inter-Pharmacy Exchange of Medicinal Products

Inter-pharmacy exchange of medicinal products is only permitted, by the regulations, when it is necessary to meet the immediate prescription needs of an individual patient. A detailed documented trail of any such exchanges should be maintained. This documentation should be signed off by a pharmacist in both the lending and receiving pharmacies and a copy should be retained in both pharmacies.

The documentation should include details of the medicinal product(s) involved, quantity supplied, batch number, expiry date, supplier (wholesaler or manufacturer), date of supply, the lending and recipient pharmacy and the reason for the exchange. When stock is obtained from another pharmacy, every effort should be made to assure the quality of the medicinal product(s) obtained. Only the amount of stock required to meet the immediate prescription needs of an individual patient, or the nearest size original pack, should be transferred.

It is important to take extra care when dealing with controlled drugs, due to the nature of the medicinal products involved and the legal requirements for record keeping etc. The receiving pharmacy should requisition the lending pharmacy and the lending pharmacy should provide a signed copy of the documentation outlined above to the receiving pharmacy. The requisition should be of the format set out in article 14 of the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017). Any CD2 medicinal products⁶ entering or leaving the pharmacy in the manner outlined must be recorded in the controlled drugs register.

4 Copies of invoices are appropriate where there is no other legislative requirement to keep the original invoice.

5 PSI Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business.

6 Controlled Drugs (CDs) listed in Schedule 2 of the Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017).

3.2 Medicinal Products which may be Sold or Supplied from a Pharmacy

Regulations 8 and 11 set out the requirements regarding the medicinal products, including veterinary medicinal products, which may be sold or supplied from a pharmacy.

Regulation 8:

Medicinal products which may be sold or supplied

8.(1) *Subject to paragraph (2), a person carrying on a retail pharmacy business shall not sell or supply a medicinal product (including a medicinal product on a general sales list) unless—*

(a) *there has been granted in respect of such product a marketing authorisation which is for the time being in force, or*

(b) *the said product is not required to be the subject of such a marketing authorisation by virtue of Regulation 6(4) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).*

(2) *Paragraph (1)(a) shall not apply until the 30 April 2011 in the case of—*

(a) *traditional herbal medicinal products, or*

(b) *homeopathic medicinal products to which Regulation 11 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) applies, which were on the market in the State on 20 July 2007.*

Regulation 11

Veterinary medicinal products which may be sold or supplied

11. *A person carrying on a retail pharmacy business shall not sell or supply a veterinary medicinal product unless—*

(a) *the sale or supply of the said product is in accordance with the requirements of Regulation 28(1) of the animal remedies regulations,*

(b) *the sale or supply of the said product is in accordance with Regulation 28(4) (a) of the animal remedies regulations, except where Regulation 44 of the said regulations applies and has been complied with, and*

(c) (i) *there has been granted in respect of such product an animal remedies authorisation which is for the time being in force, or*

(ii) *the said product is not required to be the subject of an animal remedies authorisation by virtue of Regulation 3(2) of the animal remedies regulations, or*

(iii) *it has been determined by the Board that the said product is not required to be the subject of an animal remedies authorisation by virtue of Regulation 3(3) of the animal remedies regulations, or*

(iv) *there has been granted in respect of the product by the Minister for Agriculture, Fisheries and Food, a license, pursuant to Regulation 18(11)(c) of the animal remedies regulations, which is for the time being in force, or*

(v) *it is a product within the meaning of Regulation 18(2)(c)(ii) or Regulation 18(9) (c)(ii) of the animal remedies regulations.*

3.2.1 Marketing Authorisations

All medicinal products sold or supplied from a pharmacy must be appropriately authorised, unless exempted from such a requirement, to ensure the quality, safety and efficacy of the medicinal product. Pharmacies must obtain their medicinal products from authorised suppliers and each medicinal product should be checked on receipt for an authorisation number and appropriate packaging. The authorisation status of any medicinal product or of any wholesaler or manufacturer can be clarified with the HPRA.

Under European and Irish legislation, all medicinal products must be authorised before being placed on the market. The types of marketing authorisations a medicinal product may hold are⁷:

- (a) **An Irish Marketing Authorisation (previously called a Product Authorisation), denoted by a 'PA' number.** Medicinal products on the market in Ireland must be authorised by the HPRA. A medicinal product which has a **Marketing Authorisation** granted by the HPRA is authorised for sale in Ireland and is identified by the letters 'PA' in front of the authorisation number, e.g. PAxxxx/xxx/xxx. A marketing authorisation for a veterinary medicinal product is identified by the letters '**VP**A' in front of the authorisation number.
- (b) **A Community Marketing Authorisation denoted by an 'EU' number.** A medicinal product may have a **Community Marketing Authorisation** granted by the European Commission. A community marketing authorisation is identified by the letters '**EU**' in front of the authorisation number, e.g. EU/x/xx/xxx/xxx. A medicinal product with an 'EU' number is authorised for sale in all EU/EEA Member States and must be labelled with the approved product labelling and leaflets for the specific market. The approved language for Ireland is English. (Section (e) deals with the parallel distribution of these medicinal products).
- (c) **A Parallel Product Authorisation denoted by a 'PPA' number.** A medicinal product may have a **Parallel Product Authorisation**. Parallel-importation is the importation of a medicinal product, authorised both in Ireland and another EU/EEA Member State, from that EU/ EEA Member State by an importer who is someone other than the importer appointed by the marketing authorisation holder for the medicinal product in the Irish market. The imported medicinal product may then be parallel-distributed in Ireland provided that the importer obtains an authorisation to market the product from the HPRA. An authorisation for a parallel-distributed medicinal product is identified by the letters '**PPA**' in front of the authorisation number, e.g. PPAxxxx/xxx/xxx. An authorisation for a parallel-distributed veterinary medicinal product is identified by the letters '**PVPA**' in front of the authorisation number. Further information on the licensing of parallel-imported products is available on the HPRA website.
- (d) **A Dual Pack Import registration.** Medicinal products on the market in Ireland may have a **Dual Pack Import Registration**, granted by the HPRA. This applies to the parallel-import of a medicinal product which is identical in all respects (including identical packaging, labels and leaflets) to the product on the Irish market, which is packaged in dual-market, identical packaging and which carries the marketing authorisation numbers of both countries, i.e. the source country and Ireland. Therefore, such products must have a 'PA' number on the packaging and may also have a 'PL' number if the medicinal product is authorised in the UK or a 'MA' number if the medicinal product is authorised in Malta, i.e. the Member States whose packaging and leaflets are also written in English. A wholesaler must be licensed by the HPRA to distribute such products and the wholesaler should have a dual-pack registration '**DPR**' number on record for each medicinal product. All DPR medicinal products supplied by wholesalers are over-printed/

over-labelled to denote the DPR number and the parallel importer for the product. A person conducting a pharmacy must take extra care when ordering dual pack registered medicinal products and must be satisfied that the products are appropriately authorised for sale in Ireland. If any doubt exists regarding the authorisation status of a medicinal product, its status should be checked with the HPRA.

- (e) **Parallel-distribution within the EU of medicinal products authorised by the European Commission.** Medicinal products authorised by the European Commission are granted a Community Marketing Authorisation denoted by an 'EU' number. These medicinal products may be parallel-distributed within the EU by a parallel distributor. The label of such products indicates the parallel distributor, the repackager (if repackaging has been carried out) and the manufacturer or the marketing authorisation holder. Importers wishing to parallel distribute these medicinal products in Ireland must notify the European Medicines Agency (EMA) and the HPRA. A list of these notifications is posted on the website of the EMA (www.ema.europa.eu). Each notification includes information on the specific medicinal product which is being parallel distributed.

In summary, a pharmacist must not sell or supply a medicinal product unless it has been correctly authorised, or is an 'exempt' medicinal product. Correctly authorised medicinal products carry a 'PA', a 'VPA', an 'EU', a 'PPA' or a 'PVPA' number. Some medicinal products may also have additional numbers, e.g. DPR medicinal products. Medicinal products that have been parallel imported/distributed should have a 'PPA', 'PVPA' or 'EU' number and may have additional details included, depending on the route of authorisation.

3.2.2 Veterinary Medicinal Products

Requirements related to the veterinary medicinal products which may be sold or supplied from a pharmacy are set out in the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007) (as amended) and further information on these requirements is available from the HPRA.

3.2.3 Medicinal Products Exempted from the Requirement to be Authorised – 'Exempt' Medicinal Products

Notwithstanding the marketing authorisations outlined above, Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No.540 of 2007) (as amended) includes an exemption for the supply of an unauthorised medicinal product in response to a bona fide unsolicited order from a practitioner. This exemption allows for the supply of an unauthorised product in response to a prescription from a practitioner, i.e. a registered doctor or a registered dentist, for an individual patient under his or her direct responsibility, in order to fulfil the special needs of the patient. Such products are defined as 'exempt' medicinal products. These products were previously known as 'unauthorised' or 'unlicensed' medicinal products. A medicinal product can only be defined as 'exempt' when it is supplied to the order of a registered practitioner for use by a patient under his or her direct care⁸.

Any 'exempt' medicinal product ordered must only be sourced from manufacturers and wholesalers authorised to supply such products. These suppliers must be authorised within the EEA. A list of manufacturers and wholesalers used should be maintained in the pharmacy.

Pharmacists should ensure they keep themselves informed of any requirements regarding the sourcing of 'exempt' medicinal products, e.g. HPRA requirements.

To ensure full traceability, documentation should be available in the pharmacy which permits clear identification of the supplier of each 'exempt' medicinal product, e.g. supplier invoices⁹, delivery dockets. There are additional record-keeping requirements for the sale and supply of 'exempt' medicinal products set out in paragraph 7 of Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) (as amended)¹⁰.

Pharmacists should only keep an appropriate level of stock of any 'exempt' medicinal product to meet normative patient needs, e.g. one month's supply plus broken bulk per patient prescribed the medicinal product.

When a pharmacist receives a prescription for an 'exempt' medicinal product, the pharmacist should ensure that the prescribing practitioner is aware of the unauthorised status of the product. The pharmacist should, where possible, inform the practitioner why the medicinal product is unauthorised, for example, if the medicinal product was recently withdrawn from the Irish market. A record, outlining that this information has been imparted, should be inserted in the patient's file.

Pharmacists should be aware, and should inform prescribers, that 'exempt' medicinal products should not be sourced and supplied if a suitable authorised alternative is available in Ireland.

In circumstances where, due to a medicinal product being in short supply, a pharmacist has dispensed an 'exempt' medicinal product in response to a prescription for an authorised product, the pharmacist should check, prior to each supply, if the authorised medicinal product has become available again. It is important to always inform and obtain the consent of the prescriber prior to supplying an unauthorised medicinal product on foot of his or her prescription.

Patients, or their carers, should be appropriately informed of the unauthorised or 'exempt' status of the medicinal product. They should be made aware of what this

means and given the necessary reassurances, as appropriate. A record, outlining that this information has been imparted, should be inserted in the patient's file.

Pharmacists should also be cognisant of the availability of information on the medicinal product in English and, where possible, supply the patient with a patient information leaflet or other written information. Pharmacists should ensure patients are informed that any information provided is from another jurisdiction. If no patient information is available in English, the pharmacist should ensure that they can counsel the patient on the correct use of the product.

3.3 Withdrawal or Recall of Medicinal Products from the Market

Regulation 5(1)(g) sets out the requirements regarding the withdrawal or recall of medicinal products from the market.

Regulation 5(1)(g):

5.(1) The pharmacy owner and the superintendent pharmacist shall, inter alia, ensure that—

(g) he or she co-operates with the directions of the Board, or other such authority, in respect of the withdrawal or recall from sale or supply of any medicinal product, or veterinary medicinal product, as may be given, or as may be implemented, by the Board,

A medicinal product withdrawal/recall procedure should be developed, documented and regularly reviewed to ensure that a pharmacy can respond quickly to a request from the marketing authorisation holder, in agreement with the competent authority (the HPRA), to withdraw or recall any medicinal product from sale. The recall procedure should be regularly challenged to verify effectiveness and should consider all aspects of a potential recall or withdrawal situation including those that extend to patient level.

⁹ Copies of invoices are appropriate where there is no other legislative requirement to keep the original invoice.

¹⁰ These requirements will be dealt with in more detail in future guidelines, for example, those on record keeping.

The procedure should be actioned as soon as possible following notification of a recall or withdrawal. Records detailing the recall should be maintained.

All stock of the medicinal product subject to a recall should be segregated from general stock, i.e. stored in a designated quarantine area of the pharmacy and clearly labelled. Such products should be processed in accordance with the directions of the marketing authorisation holder and/or the HPRAs.

On receipt of a recall letter, documentation related to the inter-pharmacy exchange of medicinal products should be reviewed and if any of the medicinal products transferred are the subject of the recall, the pharmacy supplied should be alerted and a copy of the recall letter provided.

3.4. Policies and Procedures

Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of the sourcing of medicinal products outlined in these guidelines. These procedures should outline the processes involved in the verification of the authenticity of suppliers and medicinal products and the ordering, receipt, checking and entering into stock of medicinal products. Specific written procedures should be in place for the sourcing of 'exempt' medicinal products, the segregation and disposal of patient-returned medicinal products, the inter-pharmacy exchange of medicinal products and the withdrawal or recall of medicinal products from the market.

The procedure for the receipt of medicinal products should state the processes involved in the receipt and examination of new stock prior to its addition to existing pharmacy stock. These checks should include, but are not limited to, verification that each medicinal product is appropriately authorised, appropriately intact and within its shelf life. In addition to these checks, procedures for the receipt of medicines should ensure that medicinal products requiring particular storage conditions, e.g. products requiring refrigeration or controlled drugs, are given immediate

priority by the staff that are authorised to accept their delivery.

All procedures should state the persons involved in the process and be signed by such persons. The staff involved in a particular procedure should be trained in the relevant procedure and records of such training maintained.

All policies and procedures should state their implementation date and the review date. The superintendent and supervising pharmacists should ensure they are reviewed regularly, i.e. when any element of the process changes, and at a minimum annually. When a review takes place, the review should be documented, i.e. dated and signed by the appropriate person, and the policy or procedure should be updated if necessary. The relevant staff members must be made aware of any amendments, appropriately trained, and the updated policies and procedures should be signed by such persons.

3.5 Particular Care Settings

All retail pharmacy businesses must comply with these guidelines. In particular care settings, e.g. where a retail pharmacy business is located within a hospital, it may be appropriate to put alternative policies and procedures in place in respect of specific aspects of the guidelines. Such policies and procedures should take account of all legal and professional responsibilities. It may be necessary, for certain aspects of practice, to work with other healthcare professionals to put interdisciplinary policies and procedures in place.

Where such alternative policies and procedures are in place, in particular care settings, the PSI expects the superintendent pharmacist, supervising pharmacist, any relevant registered pharmacist and the pharmacy owner to act in the best interest of patients and to ensure the integrity of the final link in the supply chain for a medicinal product, from the manufacturer to the patient, is maintained. Any deviation from the guidelines and the justification for such deviation should be recorded.

4. Legislative References

- Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008).

- Pharmacy Act 2007.

- Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) (as amended).

- Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017).

- Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended).

- European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No.786 of 2007) (as amended).

Relevant legislation can be accessed through the PSI website www.psi.ie, and is also available from www.irishstatutebook.ie.

| Version Number | Date Issued |
|----------------|--------------|
| 1 | May 2011 |
| 2 | October 2017 |

5. Self-assessment Checklist

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

| Ask Yourself | Yes | No | N/A | Required Action |
|---|-----|----|-----|-----------------|
| Are all relevant staff aware of, and trained in, the pharmacy's policies and are training records maintained? | | | | |
| Do all pharmacy procedures state the staff involved in the process, are they signed by such staff, are such staff trained and are training records maintained? | | | | |
| Does each policy and procedure state its implementation and review date and are these documents reviewed regularly, i.e. when any element of the process changes and, at a minimum, annually? | | | | |
| Is the review of a policy or procedure documented, i.e. signed and dated, and the policy or procedure updated, if necessary, and are all relevant staff members made aware of any amendments, appropriately trained and records of the training maintained? | | | | |
| Are all medicinal products, including veterinary medicinal products and all non-prescription medicinal products, sourced from authorised manufacturers or wholesalers? | | | | |
| Is there a list of all manufacturers and wholesalers, from whom medicinal products are sourced and whose authorisation has been verified, maintained in the pharmacy? | | | | |
| Is documentation retained in the pharmacy which permits clear identification of each consignment of medicinal products received and of the medicinal products therein, e.g. suppliers' invoices? | | | | |
| Are all staff involved in the sourcing and ordering of medicinal products aware of the types of marketing authorisations a medicinal product may have and are all medicinal products checked on receipt from suppliers? | | | | |
| Does inter-pharmacy exchange of medicinal products only occur when necessary to meet the immediate prescription needs of an individual patient, and is a documented trail of all inter-pharmacy exchanges, with the appropriate details, maintained? | | | | |

| Ask Yourself | Yes | No | N/A | Required Action |
|--|-----|----|-----|-----------------|
| Does the inter-pharmacy exchange of Schedule 2 controlled drugs only occur on foot of an appropriately written requisition and are such exchanges always recorded in the CD register? | | | | |
| Are there policies and procedures in place for the ordering, receipt, checking (examination of authorisation, packaging, expiry date, batch number etc.) and entering into stock of medicinal products? | | | | |
| Do the pharmacy's receipt procedures deal specifically with the receipt, examination and immediate processing of refrigerated medicinal products and CDs (the relevant CDs must be placed in the CD safe and recorded in the CD register)? | | | | |
| Are all pharmacy staff aware of the necessity to contact the HPRA if they suspect counterfeit, inappropriately authorised or defective medicinal products, and to quarantine such stock appropriately? | | | | |
| Is there a specific written procedure in place for sourcing 'exempt' medicinal products, is a list of appropriately authorised suppliers maintained and is documentation retained in the pharmacy which permits identification of these suppliers? | | | | |
| Does the pharmacist always ensure the prescriber is aware that a medicinal product is unauthorised, inform the prescriber of the availability of any suitably authorised alternative and note this in the patient's file? | | | | |
| Are patients always informed of the unauthorised or 'exempt' status of a medicinal product, made aware of what this means, provided with counselling, information and necessary reassurances, as appropriate, and is this noted in the patient's file? | | | | |
| Is there a withdrawal/recall procedure in place which ensures the pharmacy can respond quickly to the recall of any medicinal product, including to patient level, is it regularly challenged and are records of all recalls maintained in the pharmacy? | | | | |
| Are all medicines subject to a recall appropriately quarantined and processed in accordance with the directions of the marketing authorisation holder and/or the HPRA? | | | | |