HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to

New Applications and Variations to Wholesale Distribution Authorisations

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

INTRODUCTION

This document provides guidance on applying to the Health Products Regulatory Authority (HPRA) for a new wholesale distribution authorisation (WDA) or to vary an existing WDA.

This guide should be read in conjunction with the relevant application form:

- 'Application for a wholesale distribution authorisation' (AUT-F0199)
- 'Application to vary a wholesale distribution authorisation' (AUT-F0792)

The WDA is formatted into the agreed EU format included in the Compilation of Union Procedures on Inspections and Exchange of Information published by the European Medicines Agency on behalf of the European Commission. Guidance on the regulations covering wholesale distribution in Ireland can be found in the 'Guide to Wholesaling and Brokering of Medicinal Products for Human Use in Ireland' (IA-G0008) and the 'Guide to Good Distribution Practice of Medicinal Products for Human Use' (IA-G0046) on the regulatory information page of the HPRA website, www.hpra.ie.

GENERAL REQUIREMENTS FOR A WHOLESALE DISTRIBUTION AUTHORISATION (WDA)

To grant a WDA, the wholesaler must have a permanent physical site in Ireland where the wholesaling activities take place, for which the WDA will be valid. Wholesaling activities must take place at the site and the necessary equipment to conduct the wholesaling activities must be located there. The wholesaling site must be accessible at all times to the HPRA.

Records of the wholesaling activities must be readily available at the wholesaling site at all times, and the HPRA must be able to access those records at the site. If records are electronic, it must still be possible for the HPRA to access them at the site at all times through the wholesaler's equipment.

There must be appropriate and sufficient staff at the authorised site where the wholesaling activities occur. A minimum of one staff member that is based in Ireland, available to attend the site as required and to assist the HPRA in the event of an announced or unannounced inspection is essential. This staff member must be continuously contactable, have a thorough understanding of the wholesaling activities and access to the associated records. If this staff member is not formally named on the authorisation, contact details for the nominated individual should be provided via email to the HPRA's Compliance department without delay and captured in a controlled manner within the company's quality management system.

In line with paragraph 5.2 of the EU Guide to Good Manufacturing Practice, and Article 40 of Directive 2001/83/EC, wholesale distributors physically receiving medicinal products from third

countries for the purpose of physical importation, i.e. for the purpose of placing these products on the EU market, must hold a manufacturing authorisation. Therefore, a WDA cannot be granted for the physical importation of medicinal products. However, the onward supply of these products, where the importing manufacturer is not the manufacturer of that specific product, requires a wholesale distribution authorisation.

Please refer to the HPRA 'Guide to Wholesaling and Brokering of Medicinal Products for Human Use in Ireland' and the Wholesale Distribution of Medicines section of the HPRA website for more information on what constitutes wholesaling activities in Ireland. Notes related to 'procure' and 'supply' only and 'procure', 'supply' and export only applications have been highlighted throughout this guide.

PROGRESSION OF VARIATIONS

The application to vary a wholesale distribution authorisation form is used for the standard variation process. This form is divided into three sections, depending on the assessment type (administrative or technical) and applicable timeline (30 or 60 calendar days). The HPRA will progress the approval and authorisation of variations in accordance with the assessment timeline as outlined below, provided that:

- Acceptable supporting information/documentation is supplied without delay through the application form and requested responses.
- Progression of such variation(s) is not dependent on the approval of a linked variation(s) or the closure of an inspection.

Linked variations must be processed together, e.g. Removal of Responsible Person variation has an assessment timeline of 30 calendar days; however, progression of this removal is only possible when a suitable replacement is approved. The assessment timeline for addition of RP or change in role from Deputy Responsible Person to Responsible Person is 60 calendar days.

An inspection may take place as part of the assessment for any variation type, in particular those indicated by an asterisk*. In such instances, the timeline is 90 calendar days. Any applicants submitting a variation of this type are expected to be ready for inspection at the time of application, and applications will be deemed incomplete if this is not the case. Variations must be approved by the HPRA prior to implementation.

Administrative variations (30-day procedure)

General information:

- Minor correction/typographical error to authorisation

Applicant details:

- Change in name of authorisation holder
- Change in legally registered address of the authorisation holder
- Change in name of the wholesaling premises of the authorisation holder

Annex 1:

- Removal of category of medicinal product
- Removal of wholesale distribution operation
- Removal of category of medicinal product with additional requirements

Annex 2:

- Removal of contract wholesale distribution site
- Change in name or authorisation number of contract wholesale distribution site

Annex 3:

- Removal of Deputy Responsible Person (DRP)
- Removal of Responsible Person (RP)
- Change in role of Responsible Person to Deputy Responsible Person (RP to DRP)

Technical variations (30-day procedure, 90 days if inspection required)

Applicant details:

- Change in address of the wholesaling premises of the authorisation holder

Annex 1:

- Addition of category of medicinal product
- Addition of wholesale distribution operation
- Addition of category of medicinal product with additional requirements

Technical variations (60-day procedure)

Annex 2:

- Addition of contract wholesale distribution site
- Change in address of contract wholesale distribution site

Annex 3:

- Addition of Deputy Responsible Person (DRP)
- Addition of Responsible Person (RP)

- Change in role of Deputy Responsible Person to Responsible Person (DRP to RP)

APPLICANT DETAILS

The applicant is required to provide evidence of the authorisation holder's legally registered address (e.g. Certificate of Incorporation from the Companies Registration Office). This address may differ from the address where wholesaling activities take place; however, if the legally registered address of the applicant is different from the proposed wholesaling site and wholesaling activities occur at the legally registered address, a separate WDA is required. This includes when applicants only intend to complete procurement and supply activities or procure, supply and export at the legally registered address. A business name (also known as a trading style) is where the name used to carry on business by any individual, body corporate or partnership (whether of individuals and/or bodies corporate), at a place of business in the Republic of Ireland, is not the same as their company registered name(s). Evidence of registration of the business name with the Companies Registration Office should also be provided.

Guidance on addresses

The applicant must register the legally registered address and address of site with the EMA's SPOR Organisation Management Service (OMS) before submitting a new application for a wholesale distribution authorisation to the HPRA. If organisation and location IDs for these addresses are not provided in a new application for a wholesale distribution authorisation, the form will be deemed incomplete and returned to the applicant. For further information on this registration, please refer to the learning materials from the EMA listed below:

- Organisation Management Service (OMS)
- SPOR Data Management Service portal
- Video tutorial: Overview of OMS
- Webinar for Industry: Introduction to OMS services and activities

If the address details for a registered authorisation holder on EMA SPOR – OMS are not aligned with the existing HPRA authorisation, a change request should be raised on EMA SPOR - OMS to address the discrepancies where possible.

- In the event that approval for this change is granted, evidence of this approval should be submitted with the application to vary the authorisation.
- In the event that approval for this change is rejected, due to underlying differences in the address information from the national postal service, the application may be deemed acceptable if the named RP can provide the following information via email:

- Evidence of the rejection that was received.
- Proposed action(s) to address the underlying differences if not through EMA SPOR directly, for example through follow up with the national postal service or CORE.
- Proposed timeline for implementation or delivery of update on the outcome of any proposed action(s).
- Confirmation of acceptance for the EMA SPOR details and a clarifying remark that will be added to the new authorisation by the HPRA in the interim until any changes can be made (if any).

Proposed variations to applicant details

Variation type	Supporting documentation to be submitted
Minor corrections/ typographical errors to authorisation	Signed variation application form outlining the nature of the typographical error.
Change in the name of authorisation holder	Certificate of Incorporation. Signed statement from the RP named on the authorisation, or a statement included in the application form signed by the RP, outlining any implications that this change may have on the quality management system or its operation at the site.
Change in the legally registered address of the authorisation holder	Updated Certificate of Incorporation. Signed statement from the RP named on the authorisation, or a statement included in the application form signed by the RP, outlining any implications that this change may have on the quality management system or its operation at the site.
Change in the name of the wholesaling premises of the authorisation holder	Formal document from a relevant official body (e.g. Chamber of Commerce) in which the new name is mentioned.
Change in address of the wholesaling premises of the authorisation holder	Signed statement from the RP named on the authorisation, or statement included in the application form signed by the RP, outlining any implications that this change may have on the quality management system or its operation at the site, particularly holding of medicinal products if holding is part of the scope of wholesale distribution authorisation. Note: an inspection may also take place as part of the assessment of such a variation.

ANNEXES FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Annex no.	Annex title	Notes
Annex 1	Scope of wholesale distribution authorisation	This describes the scope of wholesale distribution operations which are carried out directly under this authorisation only.
Annex 2	Address(es) of contract wholesale distribution sites and their authorisation number(s)	This annex contains the name, address and authorisation number(s) of any contract site that performs wholesale distribution operations on behalf of the authorisation holder.
Annex 3	Name(s) of Responsible Person(s)	This information is not published on the EudraGMDP database.

ANNEX 1 SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Part 1 Medicinal products

The application should contain details of the proposed category of medicinal product as defined below.

With a Marketing Authorisation in EEA country(s)

Products with a marketing authorisation in Ireland or another EEA country(ies).

Without a Marketing Authorisation in the EEA and intended for EEA market

(Article 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004)

Products without a marketing authorisation in EEA country(ies) and intended for supply to a EEA country(ies).

Without a Marketing Authorisation in the EEA and intended for exportation

Products without a marketing authorisation in EEA country(ies) and intended for exportation outside of the EEA.

Part 2 Authorised wholesale distribution operations

(Relating to Schedule 1 of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007, as amended)

Handling procedures related to each of the below wholesale distribution operations and qualification reports should be available, upon request, during the assessment of the application.

2.1 Procurement

Procurement relates to obtaining, acquiring, purchasing or buying medicinal products from manufacturers or other wholesale distributors.

2.2 Holding

Holding relates to the physical storage of medicinal products. To support applications for holding of products, conclusions of a temperature mapping study or risk assessment as applicable should be available and may be requested to ensure inspection readiness.

2.3 Supply

Supply refers to all activities of providing, selling or donating medicinal products to wholesalers; pharmacists; or persons authorised or entitled to supply medicinal products to the public.

2.4 Export

Export relates to the supply of a medicinal product to a state other than an EU Member State or a Contracting State of the European Economic Area.

Notes related to 'procure' and 'supply' only applications and 'procure, supply' and 'export' only applications

To support 'procure' and 'supply' only application and 'procure, supply' and 'export' only applications, the wholesaler must have evidence available to demonstrate that proposed activities meet the requirements of the definition of 'Procurement' and 'Supply', as defined above. In essence, the wholesale entity must be able to show that it is in fact performing wholesale activities at the site and that it 'takes title' of the product at some point in the supply model proposed.

Evidence may include draft/mock invoices, purchase orders, or other documents showing that the wholesaler owns or has title of the product such as demonstration of stock movement on a stock inventory management system, financial ownership such as bank accounts registered in the name and address of the wholesaling site. It is understood that exact customers and suppliers may not be known at the time of a new application; however, a robust business model must be in place to support the application. The expectation is that a technical agreement and audit report for each contract storage site is available.

Part 3 Medicinal products with additional requirements

Essential guidance documents for wholesaling and brokering in Ireland are available from the Wholesale Distribution of Medicines page of the HPRA website. For the addition of any category of medicinal products with additional requirements to the scope of an existing wholesale distribution authorisation, applicants should thoroughly review the HPRA 'Guide to Good Distribution Practice of Medicinal Products for Human Use', applicable legislation and any other sections of the HPRA website which outline additional regulatory requirements of relevance to the addition(s). The company should provide a reason for this addition(s), any implications that this change(s) may have on the quality management system or its operation at the site and how the site plans to manage this implication(s). The relevant procedure(s) for handling the proposed category of medicinal product(s) at the site should be available and may be requested during the assessment of the application for further review, in particular for parallel imported products, exempt medicinal products or unauthorised medicinal products.

The categories of medicinal products with additional requirements are detailed below:

3.1 Narcotic or psychotropic products

Please be aware that a separate licence/registration is required to wholesale controlled drugs. Refer to the Regulation of controlled drugs page of the HPRA website for more information.

3.2 Products requiring low temperature handling (formerly 'Cold chain products')

3.2.1 Temperatures between 2 and 8 degrees Celsius

3.2.2 Temperatures below 0 degrees Celsius

3.3 Other products

3.3.1 Prescription only medicinal products

3.3.2 Medicinal products for general sale

Refer to the HPRA 'Guide to Quality System for General Sale Wholesale Distributors' for more information.

3.3.3 Over the counter medicinal products for sale through pharmacies only

3.3.4 Unauthorised medicinal products

Unauthorised medicinal products are products which do not hold a marketing authorisation for Ireland or central authorisation for the EEA that are intended for supply to a market outside of Ireland. A wholesaler may supply such products only to markets outside of Ireland where the products are authorised, or to markets where the product is not authorised if permitted to do so under that territory's regulatory framework. Unauthorised medicinal products are not for supply on the Irish market.

3.3.5 Vaccines

3.3.6 Parallel imported medicinal products authorised by Parallel Product Authorisation (PPA)

3.3.7 Parallel imported medicinal product authorised by Dual Pack Registration (DPR)

Refer to the HPRA 'Guide to Parallel Imports of Human Medicines' for more information.

3.3.8 Parallel distributed centrally authorised medicinal products

3.3.9 Traditional herbal medicinal products

3.3.10 Homeopathic medicinal products (HOR and HOA)

3.3.11 Exempt medicinal products

An exempt medicinal product is a medicinal product which does not hold a product authorisation for Ireland or central authorisation for the EEA but is intended for supply to the Irish market. It is supplied in response to a *bona fide* unsolicited order formulated in accordance with the specification of a practitioner for use by their individual patients on their direct personal responsibility. Refer to the 'Guide to the Notification System for Exempt Medicinal Products' and the exempt medicinal products page on the HPRA website for more information.

3.3.12 Biological products

3.3.13 Advanced therapy medicinal products

3.3.14 Medicinal gases

3.3.15 Medicinal products derived from blood

3.3.16 Immunological medicinal products

3.3.17 Radiopharmaceuticals (including radionuclide kits)

Variations to Annex 1 scope of wholesale distribution authorisation

Variation type	Supporting documentation
Addition of category of medicinal product	As per guidance in Annex 1 part 1. Note: an inspection may also take place as part of the assessment of this variation.
Addition of wholesale distribution operation	As per guidance in Annex 1 part 2. Note: an inspection may also take place as part of the assessment of this variation.
Addition of category of medicinal product with additional requirements.	As per guidance in Annex 1 part 3. Note: an inspection may also take place as part of the assessment of this variation.
Removal of category of medicinal product	None required
Removal of wholesale distribution operation	None required.
Removal of category of medicinal product with additional requirements.	None required

ANNEX 2 CONTRACT WHOLESALE DISTRIBUTION SITE(S)

(Relating to Schedule 1- 4(3) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007, as amended)

Any contract wholesale distribution site proposed for addition under Annex 2 of an authorisation should be a WDA/MIA holder located in Ireland or within the EEA.

Applicants must submit the following details for **each** contract wholesale distribution site:

- The name and address of all contract distribution/storage sites and their corresponding wholesale authorisation number as registered in EudraGMDP when possible.
- Confirmation of categories of medicinal product intended for storage at the contract site and evidence for how it has been confirmed that there is appropriate authorisation at the contract site for all categories of products:
  - Where a WDA holder is proposed, the site should be authorised for the relevant category of medicinal product intended for storage at the contract site. Refer to the HPRA 'Guide to Good Distribution Practice of Medicinal Products for Human Use' for more information.
  - Where a MIA holder is proposed, the site should be authorised to conduct relevant manufacturing activities for the specific product in question at the site.
- Confirmation that a technical agreement between both parties will be in place and ready for review, upon request.
- Confirmation of completion of a GDP audit of the proposed contract site or timeline for completion of a GDP audit.
- Where the proposed contract storage site is located outside of Ireland, a copy of the original authorisation issued by the national competent authority clearly stating the authorisation number, and any additional documentation of relevance to the addition, such as:
  - A separate English translation of the documentation completed by an independent third party may be required where a document does not include an English translation in the body.
  - A license to physically hold controlled drugs, for example, may be required where the relevant category of medicinal product intended for storage at the proposed contract site is narcotic or psychotropic products.
  - A valid GDP/GMP certificate as applicable to the proposed contract site
  - Note: EudraGMDP copies will only be acceptable in lieu of the above where the national competent authority located outside of Ireland does not issue hard copies of the authorisation and this has been independently confirmed.

Notes related to 'procure' and 'supply' only applications and 'procure, supply' and 'export' only applications

A contract wholesale distribution site must be named for all applications from all applicants not authorised to 'hold' medicinal products under Annex 1 Part 2. There are no exceptions to this requirement.

Variations to Annex 2 contract wholesale distribution sites

Variation type	Supporting documentation
Addition of contract wholesale distribution site	As per guidance for Annex 2.
Removal of contract wholesale distribution site	Confirmation that the authorisation holder, or an authorised contract wholesale distribution site remaining on the wholesaler's authorisation, is appropriately authorised for holding of each category of medicinal product previously stored at the contract wholesale distribution site. A minimum of one contract wholesale distribution site is required for any authorisation without the wholesale operation of holding in the scope.
Change in name or authorisation number of contract wholesale distribution site	Submit a formal document from a relevant official body (e.g. Companies Registration Office or Chamber of Commerce or equivalent) in which the new name is mentioned. Submit a statement from an RP named on the wholesaler's authorisation regarding any implications that this change may have on the quality management system or its operation at the contracted site.
Change in address of contract wholesale distribution site	As per guidance for Annex 2.

ANNEX 3 RESPONSIBLE PERSON(S)

(Relating to Schedule 1 – 5(1&2) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007, as amended)

Any Responsible Person (RP)/Deputy Responsible Person (DRP) proposed for addition under Annex 3 of an authorisation should be experienced in the scope of the authorisation. For example, where a site is authorised for holding and certain categories of medicinal products are concerned, ideally the proposed Responsible Person has experience of another site with this operational scope. Evidence of a minimum of six months full-time direct EU GDP experience at an authorised site is expected for the role of RP/DRP; however, all applications are assessed on a case-by-case basis using a risk-based approach.

Applicants must submit the following details for **each** proposed RP/DRP:

- Curriculum vitae which should clearly state:
  - Qualifications and registrations (registration with PSI, if applicable).
  - Any responsibilities of previous roles which provided experience or exposure to the scope of the authorisation.
  - Any responsibilities of previous roles which provided experience or exposure to the role of the RP/DRP for GDP as outlined in Chapter 2.2 of the EU GDP Guidelines.
  - Note: In the case of company employees planning to change from DRP to RP, a signed declaration of no significant changes to the CV may be submitted in support of these applications.
- Signed role profile/job description specific to the role of RP/DRP at the wholesaling site which should include:
  - Role title.
  - Address of the wholesaling site.
  - Responsibilities of the RP as outlined in Chapter 2.2 of the EU GDP Guidelines and any conditions to when delegation can take place in the case of the DRP.
  - Print name and signature from the proposed RP/DRP and manager.
  - Note: Contingencies for the handover of responsibilities should be planned for and clearly outlined in the contract in case this working relationship between the two parties should cease in the future for any reason.
- Individually dated training records within the last 12 months which should include current versions of:
  - The European Commission's Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01).
  - Relevant national legislation.
  - Procedures (SOPs) specific to the wholesaler's quality system.
  - HPRA Guide to New Applications and Variations to Wholesale Distribution Authorisations (WDAs) (AUT-G0152).

  - HPRA Guide for Recall of Medicinal Products for Human and Veterinary Use (SUR-G0019).
  - HPRA Guide to Good Distribution Practice of Medicinal Products for Human Use (IA-G0046).
  - HPRA Guide to Wholesaling and Brokering of Medicinal Products for Human Use in Ireland (IA-G0008).
  - HPRA Guide to Quality System for General Sale Wholesale Distributors (IA-G0038) – where medicinal products for general sale are concerned.
  - HPRA Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances (IA-G0011) – where holding is concerned.
  - Any additional HPRA Guides of relevance to the scope of the authorisation.
  - Print name and signature from the proposed RP/DRP and trainer/manager.
  - Note: While external 'GDP'/'RP'/DRP' training courses do exist, these are considered optional, additional trainings. Record of independent reading completed by the trainee is considered sufficient once this record is dated within the last 12 months and is signed by the trainee and the trainer/manager and has been suitably assessed by the wholesaler.
- Additional requirements for use of an outsourced provider for the role of RP/DRP:
  - Confirmation that a technical agreement between both parties is in place and ready for review, upon request.
  - Confirmation of completion of a GDP audit of the proposed outsourced provider or details on the process for assessing the proposed contract RP/DRP's suitability for the role.
  - Details of the company's assessment of the proposed outsourced provider's suitability for the role entered into the table in Appendix 1 of the application form. A key for any internal client identifier number in use should be sent to the HPRA assessor separately to ongoing correspondence to verify information on wider consultancy activities while respecting clients' right to privacy. Supporting evidence for any information provided in relation to this assessment may be requested if not readily available.
  - Note: If an employee of one company is acting as RP/DRP on the WDA of another company within the same group of companies, there should be a contract or procedure in place documenting their duties and responsibilities as RP and frequency of attendance to the site. There is no requirement for such proposed RP/DRPs to complete the table in Appendix 1.

The above information should be provided in respect of each RP/DRP acting at each wholesaling premises associated with the authorisation.

Variations to Annex 3 Responsible Person(s)

Variation type	Supporting documentation
Removal of Deputy Responsible Person (DRP)	None required
Addition of Deputy Responsible Person (DRP)	As per guidance in Annex 3.

Variation type	Supporting documentation
Change of Deputy Responsible Person (DRP) to Responsible Person (RP)	As per guidance in Annex 3.
Change of Responsible Person (RP) to Deputy Responsible Person (DRP)	None required however, approval is contingent on replacement with a new RP.
Addition of Responsible Person (RP)	As per guidance in Annex 3.
Removal of Responsible Person (RP)	None required however, approval is contingent on replacement with a new RP and provision of the date of departure.

ADDITIONAL SUPPORTING INFORMATION REQUIRED FOR NEW WDA APPLICATIONS

Proposed wholesale distribution model

Applicants must submit the following details for the proposed wholesale distribution model:

Supplier types

Include details where known, such as whether the proposed supplier(s) are manufacturers or wholesalers in Ireland or another country in the European Economic Area (EEA) or outside the EEA (for financial only procurement sites).

Applicants must also be prepared to supply information regarding assessments completed to ascertain the authority of suppliers to supply medicinal products, upon request.

Customer types

Include details, where known, such as whether the customers are registered retail pharmacy businesses, hospitals, authorised wholesale distributors or authorised manufacturers in Ireland, another EEA country or outside of the EEA.

Transport model (if applicable)

Outline who has responsibility for transportation. Where the wholesaler has responsibility for transportation, validation as applicable may be reviewed during the inspection. Note transportation does not require any standalone certification in relation to GDP; it is the WDA holders responsible for transport that ensure compliance with GDP. Further information regarding the transport model and supply chain routes may be requested.

Note: It is understood that exact customers and suppliers may not be known at the time of a new application; however, please provide as much information as possible relating to the categories of potential customers and suppliers. A robust business model must be in place to

assess systems to support the application. Final stage technical agreements with future suppliers and customers may be requested as evidence of this.

Premises and equipment

(Relating to Schedule 1, 4 (2) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007, as amended.)

Please include a detailed statement indicating the facilities and equipment available at **each** of the premises referred to the applicant details section above.

Consider the following factors within this statement:

Storage:

- Warehousing capacity
- Details of the temperature monitoring system
- Details of the building management system (if applicable)
- Details of temperature/humidity controls
- Validation status of equipment and systems, e.g. details of the temperature mapping studies conducted and what conditions/parameters were assessed as part of this test

Note: for applicants who will not be physically storing product, please provide the name, address and wholesaler's authorisation number for the contract storage site(s) in Annex 2 of the application. This is the site(s) where product is stored whilst ownership of the product is maintained by the wholesaler.

Inventory control:

- Details of inventory management/stock control systems
- Details of stock rotation controls

Picking:

- Description of picking method (automated or manual)

Cold chain storage:

- Detail of fridge units and associated temperature control and monitoring systems
- Details of freezers and associated temperature control and monitoring systems
- Details of alarm and alert systems within/outside of work hours

  Details of validation status of equipment

Security arrangements:

- Details of CCTV coverage internal and external
- Details of the access controls
- Details of the security monitoring and coverage
- Details of the alarm system

Quality system

The wholesaler is required to have a quality system in place prior to inspection. The quality system is required to have a documented set of procedures which describe, in sufficient detail, all the activities which could affect the quality of the medicines. It is recommended that the applicant submits the quality manual which outlines the hierarchy of the quality management system and approach to wholesaling.

The applicant **must** submit a list of the procedures in its quality system. Where the wholesaler is part of a corporate structure or affiliate of another company, a clear distinction should be made between corporate governance procedures and those procedures specific to activities performed at the local site to be authorised. Please refer to Appendix 1 of this guide for an example of procedures that are typically expected to be encompassed within a quality system.

Brokers

If a wholesaler of medicinal products uses the service of a broker, that broker is required by the Falsified Medicines Directive to register with the HPRA. The name and address of any brokers used must be supplied with the application.

FEES/CLASSIFICATION OF FACILITY

An application fee must be submitted with each request for a wholesale distribution authorisation. An annual maintenance fee is also payable in respect of each authorisation and is related to the size of the facility.

- A large site is defined as a site supplying a wide range of medicinal products to other wholesalers, retail and hospital pharmacies, health boards, doctors, dentists and others.
- A medium site is a site supplying a limited range of medicinal products to retail and hospital pharmacies, health boards, doctors, dentists and others.
- A small site is a short line wholesaler supplying a limited range of medicinal products to a limited range of customers, typically retail and hospital pharmacies.
- For a minor site, a fee applies only to wholesalers supplying a small range of analgesics, antacids, etc. (which may be legally sold in non-pharmacy outlets) to retail outlets such as grocery shops and newsagents.

- For a 'Procure' and 'Supply' only site or 'Procure', 'Supply' and 'Export' only site, a fee applies only to wholesalers that operate on the basis of taking ownership and selling medicinal products onwards. They do not directly store or conduct other wholesaling activities.

CONTACT DETAILS

For further information or guidance, please contact:

Email: compliance@hpra.ie

Licensing Section
Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77
Tel: +353-1-6764971
Fax: +353-1-6767836

APPENDIX 1 SAMPLE PROCEDURE LIST FOR WHOLESALING QUALITY SYSTEM

SOP – RESPONSIBLE PERSON
SOP – DOCUMENTATION CONTROL
SOP – DEVIATIONS
SOP – CHANGE CONTROL
SOP – MANAGEMENT REVIEW AND MONITORING
SOP – QUALITY RISK MANAGEMENT
SOP – TRAINING
SOP – CLEANING PROCEDURE
SOP – PEST CONTROL PROGRAMME
SOP – RECEIPT OF MEDICINAL PRODUCTS
SOP – ESTABLISHING THE AUTHORITY OF SUPPLIERS TO SUPPLY MEDICINAL PRODUCTS
SOP – TEMPERATURE MAPPING AND MONITORING
SOP – STORAGE OF MEDICINAL PRODUCTS
SOP – ORDER PROCESSING, PICKING AND DISPATCH
SOP – RETURN OF MEDICINAL PRODUCTS TO INVENTORY
SOP – CUSTOMER COMPLAINTS
SOP – RECALL PROCEDURE
SOP – OUTSOURCED ACTIVITIES
SOP – SELF-INSPECTIONS
SOP – PROTOCOL FOR MANAGEMENT OF FALSIFIED MEDICINAL PRODUCTS
SOP – WASTE MANAGEMENT OF MEDICINAL PRODUCTS

APPENDIX 2 SAMPLE TIMELINE AND FEE CALCULATION

Example 1

An authorisation holder would like to submit an application to vary a single wholesale distribution authorisation that includes the following variations: an addition of Responsible Person (RP), removal of Responsible Person (RP), addition of contract wholesale distribution site and removal of Deputy Responsible Person (DRP).

The applicant should complete one application form per authorisation. The section overview table lists the variations which may be required from each section. The applicant is requested to check the box for 'Yes' beside each required variation. Where more than one of this variation can be required in a single application, there is a space for quantity to be entered e.g. one will be entered as the quantity of the required variations 'Addition of contract wholesale distribution site' and 'Removal of Deputy Responsible Person (DRP)' in this case.

An inspection is not normally deemed to be required as part of the assessment of the variations enclosed.

There are linked variations in the submitted application. Removal of Responsible Person variation which has an assessment timeline of 30 calendar days will be extended to 60 calendar days.

Provided that the application and supporting documentation are acceptable and progression of such variation(s) is not dependent on the closure of an inspection, the assessment timelines will be as follows for this application:

- 60 calendar days for addition of Responsible Person (RP), removal of Responsible Person (RP) and addition of contract wholesale distribution site.
- 30 calendar days for removal of Deputy Responsible Person (DRP).

No fee applies to an administrative variation that is consequential to a technical variation, i.e. removal of RP. Two technical fees and one administrative fee will be payable to the HPRA, i.e.:

- Technical fee: Addition of Responsible Person (RP), Addition of contract wholesale distribution site
- Administrative fee: Removal of Deputy Responsible Person (DRP).
- No fee: Removal of Responsible Person (RP).

Example 2

An authorisation holder would like to submit two applications to vary two wholesale distribution authorisations that each include the following variations: change in name of authorisation holder and three additions of category of medicinal product with additional requirements.

The applicant should complete one application form per authorisation. The section overview table lists the variations which may be required from each section. The applicant is requested to check the box for 'Yes' beside each required variation. Where more than one of this variation can be required in a single application, there is a space for quantity to be entered e.g. three will be entered as the quantity of the required variation 'Addition of category of medicinal product with additional requirements' in this case.

As an inspection may be required for the additions of category of medicinal products with additional requirements, the timeline is 30 days or 90 days from the date of inspection, where an inspection is required.

There are no linked variations in this application.

Provided that the application and supporting documentation are acceptable and progression of such variation(s) is not dependent on the closure of an inspection, the assessment timelines will be as follows for these applications:

- 30 calendar days for six 'Addition of categories of medicinal product with additional requirements'. Note that if an inspection is deemed to be required then the assessment timeline will be 90 calendar days.
- 30 calendar days for two 'Change in name of authorisation holder'.

Where the same technical variation applies to two or more authorisations, the second and subsequent applications are charged at the administrative fee code rate. In this case, there are two authorisations being assessed for the same technical variations. For this reason, the combined total of three technical fees and five administrative fees will be payable to the HPRA, i.e.:

- Technical fee: three 'Addition of category of medicinal product with additional requirements' (first authorisation of two)
- Administrative fee: two 'Change in name of authorisation holder', three 'Addition of category of medicinal product with additional requirements' (second authorisation of two)
- No fee: None