

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.



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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 (AUT-F0199 Application for a wholesale distribution authorisation, or AUT-F0792 Application to vary a wholesale distribution authorisation).

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' and the 'Guide to Good Distribution Practice of Medicinal Products for Human Use' on the [regulatory information page of the HPRA website, www.hpra.ie](http://www.hpra.ie). Please note that applications will be deemed incomplete if the applicant is not ready for inspection at the time of submission of the application. Variations must be approved by the HPRA prior to implementation.

In line with paragraph 5.2 of the EU Guide to GMP, 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.

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.

GENERAL REQUIREMENTS FOR A WHOLESALE DISTRIBUTION AUTHORISATION

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 company's equipment.

There must be appropriate and sufficient staff, with a minimum of one staff member in Ireland at the wholesaling site where the wholesaling activities occur. This staff member must have a thorough understanding of the wholesaling activities and access to the associated records. They must be continuously contactable and available to attend the site as required and assist the HPRA in the event of an announced or unannounced inspection. Their contact details must be provided to the HPRA.

*See Notes related to Procure and Supply only applications (page 7).

APPLICANT DETAILS

The wholesaler is required to provide appropriate documentation as 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. 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.

To submit an application, a completed application form (AUT-F0199 Application for a wholesale distribution authorisation, or AUT-F0792 Application to vary a wholesale distribution authorisation as relevant) should be submitted to the Licensing section of the HPRA, with the appropriate supporting documentation. The applicant must register with the EMA's Organisation Management Service (OMS) before submitting an application to the HPRA. The organisation and location ID's must be provided on the application form. If these are not provided, the form will be deemed incomplete and returned to the applicant. More information on the Organisation Management Service can be found [here](#).

Guidance on addresses

- If the legally registered address of the proposed authorisation holder is different from the proposed wholesaling site and wholesaling activities occur at the legally registered address, a separate WDA is required.
 - o This includes when applicants intend to complete procurement and supply activities only at the legally registered address.

Variations to applicant details

Variation type	Procedure type and timeline	Supporting documentation
Minor corrections/typographical errors to authorisation	Admin Timeline: 30 days	Submit a signed variation application form outlining the nature of the typographical error.
Change in the name of authorisation holder	Admin Timeline: 30 days	Submit a Certificate of Incorporation. Submit a statement from a Responsible Person (RP) named on the authorisation 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	Admin Timeline: 30 days	Submit a Certificate of Incorporation. Submit a statement from a Responsible Person (RP) named on the authorisation 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 wholesale site	Admin Timeline: 30 days	Submit a formal document from a relevant official body (e.g. Chamber of Commerce) in which the new name is mentioned.
Change in address of wholesaling premises	Technical Timeline: 90 days	Note: an inspection may also take place as part of the assessment of such a variation.

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)
- ☐ Without a Marketing Authorisation in the EEA and intended for EEA market¹
- ☐ Without a Marketing Authorisation in the EEA and intended for exportation

Variations to Annex 1, part 1 medicinal

Variation type	Procedure type and timeline	Supporting documentation
Addition of a category of medicinal product	Technical Timeline: 90 days	As per guidance for Annex 1 part 1. Note: an inspection may also take place as part of the assessment of such a variation.
Removal of a category of medicinal product	Admin Timeline: 30 days	None required.

PART 2 AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS²

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

¹ Article 5 of Directive 2001/83/EC or Art 83 of regulation EC/726/2004.

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

** as amended*

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

To support Procure and Supply activities the company must have evidence available to demonstrate that proposed activities meet the requirements of the definition of 'Procurement' and/or '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. 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.

Variations to Annex 1, part 2 authorised wholesale distribution operations

Variation type	Procedure type and timeline	Supporting documentation
Addition of wholesale distribution operations	Technical Timeline: 90 days	As per guidance in Annex 1 part 2. Note: an inspection may also take place as part of the assessment of this variation.
Deletion of wholesale distribution operations	Admin Timeline: 30 days	None required.

PART 3 MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS²

Please be aware that a separate licence/registration is required to wholesale controlled drugs. Further details are available on the HPRA website, www.hpra.ie.

For the addition of parallel imported products, exempt medicinal products or unauthorised medicinal products, relevant procedure(s) for handling these categories of medicinal product(s) at the site should be available and may be requested during the assessment of the application for further review. Further information on the regulatory requirements for these categories of product is available on the HPRA website.

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

- ☐ **3.1 Narcotic or psychotropic products**
- ☐ **3.2 Products requiring low temperature handling**
 - ☐ 3.2.1 *Temperatures between 2 to 8 °C*
 - ☐ 3.2.2 *Other temperatures (please specify):*
- ☐ **3.3 Other products**
 - ☐ 3.3.1 *Prescription only medicinal products*
 - ☐ 3.3.2 *Medicinal products for general sale*
 - ☐ 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. 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)*

Refer to the 'Guide to Parallel Imports of Human Medicines' available on the [HPRA website](http://www.hpra.ie) for more information.

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

Refer to the 'Guide to Parallel Imports of Human Medicines' available on the [HPRA website](http://www.hpra.ie) 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 in Ireland 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.

Guidance on exempt medicinal products can be found on the HPRA website ~~and in the 'Publications and Forms' section at www.hpra.ie.~~

☐ 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, part 3 medicinal products with additional requirements

Variation type	Procedure type and timeline	Supporting documentation
Addition of a category of medicinal product with additional requirements	Technical Timeline: 90 days	As per guidance for Annex 1 part 3. Note: an inspection may also take place as part of the assessment of such a variation.
Removal of a category of medicinal product	Admin Timeline: 30 days	None required.

ANNEX 2 CONTRACT WHOLESALE DISTRIBUTION SITES³

Applicants **must** submit the following details:

- The name(s) and address(es) of all contract distribution/storage sites and their corresponding wholesale authorisation number.
- Where a contract wholesale distribution site is located outside of Ireland but within the EEA, please provide a copy of the authorisation/licence issued by the relevant national Competent Authority (NCA), which clearly states the authorisation/licence number.
 - o Note the supporting authorisation must be in English and include the authorised activity.
- A contract storage/distribution site must be included for all applications for Procure and Supply only activities.
- A copy of or 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.
- Confirmation of appropriate authorisation at the contract site for all categories of products which are proposed to be stored at that site.

Note: A site that holds a valid manufacturer's authorisation that is authorised for either manufacturing or importation activities (MIA) of the product(s) in question may be named as a contract wholesale distribution site in certain circumstances.

- Supporting documentation for addition of a MIA holder to Annex 2, in the case of an EU MIA holder is a copy of the MIA and a valid GMP cert issued by an EU national competent authority.

Variations to Annex 2 contract wholesale distribution sites

Variation type	Procedure type and timeline	Supporting documentation
Addition of contract wholesale distribution site	Technical Timeline: 60 days	As per guidance for Annex 2.
Removal of contract wholesale distribution site	Admin Timeline: 30 days	None required.

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

Variation type	Procedure type and timeline	Supporting documentation
Change in name or authorisation number of contract wholesale distribution site	Admin Timeline: 30 days	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	Technical Timeline: 60 days	Copy of the contract wholesaler's authorisation. 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.

ANNEX 3 RESPONSIBLE PERSON(S)⁴

Applicants must submit the following details for **each** proposed responsible/deputy responsible person:

- *Curriculum vitae* including qualifications (registration with PSI, if applicable).
- Signed role profile/job description specific to the role of the responsible/deputy responsible person.
- Training records must be submitted for the Responsible Person(s).
 - o Training records should provide evidence of training received in the principles of Good Distribution Practice (GDP) and in relevant national legislation, HPRA guidance and procedures (SOPs) specific to the company's quality system. These records should be signed by both the trainer and the trainee.
 - o Note: Evidence of GDP training within the last 12 months is preferable.
- Confirmation in relation to contract RP.
 - o When contracted RPs are engaged by an applicant, a written confirmation should be submitted outlining how many days/hours the RP will be on site and that the RP has appropriate available time to fulfil these commitments. The information provided should clearly indicate which wholesaling premises the RP has responsibility for.

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

Variations to Annex 3 Responsible Person(s)

Variation type	Procedure type and timeline	Supporting documentation
Addition of Responsible Person or deputy Responsible Person (RP)	Technical Timeline: 60 days	As per guidance in Annex 3.
Removal of a Responsible Person or deputy Responsible Person	Admin Timeline: 30 days	None required however, a new RP should be named upon removal of the current RP.
Change of Responsible Person to deputy Responsible Person	Admin Timeline: 30 days	None required however, a new RP should be named upon removal of the current RP.
Change of deputy Responsible Person to Responsible Person	Technical Timeline: 60 days	As per guidance in Annex 3.

⁴ Relating to Schedule 1 – 5(1&2) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007*

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)

Where the applicant has responsibility for transportation, risk assessments of supply routes and transportation containers, and details of temperature verification or validation systems 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 equipment⁵

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. temperature mapping studies

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 applicant.

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:

⁵ Relating to Schedule 1, 4 (2) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007*.

- 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 contain and describe, in sufficient detail, all the activities which could affect the quality of the medicines. It is desirable that the quality manual which outlines the hierarchy of the quality management system and approach to wholesaling is submitted.

The applicant **must** submit a list of the procedures in its quality system. Where the company 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.

Additional personnel

If applicable, please provide the names, qualifications and relevant experience of any other person whose duty it will be to supervise the operations at each of the premises(es) referred to in the applicant detail section, and, in each case, the name and function of the person to whom he/she is responsible.

This includes additional personnel other than the RP/deputy RP, for example, warehouse managers and quality personnel in large operations.

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.

☐ **Large site**

A site supplying a wide range of medicinal products to other wholesalers, retail and hospital pharmacies, health boards, doctors, dentists and others.

☐ **Medium site**

A site supplying a limited range of medicinal products to retail and hospital pharmacies, health boards, doctors, dentists and others.

☐ **Small site**

A short line wholesaler supplying a limited range of medicinal products to a limited range of customers, typically retail and hospital pharmacies.

☐ **Minor site**

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.

☐ **Procurement and supply only site**

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

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APPENDIX 1 EXAMPLE 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