



Medicines & Healthcare products  
Regulatory Agency

# Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration

MHRA Guidance Note 6



Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration

© Crown Copyright 2023

Previous edition 1972. Revised, 2000, 2005, 2006, 2007, 2008 and 2014

First edition published in 2007, second edition 2014, third edition 2015, fourth edition 2017, fifth edition 2022 (Section 9 amended 2023).

MHRA

10 South Colonnade Canary Wharf

London

E14 4PU

Published by MHRA 2023

Applications for reproduction should be made in writing to:

The Copyright Unit

Her Majesty's Stationery Office

St Clements House

2-16 Colegate

Norwich

NR3 1BQ

# Contents

1	Introduction .....	4
2	Wholesale dealing or distribution .....	5
3	Brokering.....	5
4	How to register as a Broker.....	6
5	Persons requiring a Wholesale Dealer’s Licence (WDA(H)) .....	6
6	How to apply for a Wholesale Dealer’s Licence (WDA(H)) .....	9
7	Application requirements.....	9
8	Wholesale dealer’s obligations.....	10
9	Responsible Person .....	10
10	Responsible Person (Import) .....	13
11	Inspection.....	14
12	Falsified and diverted medicines .....	16
13	Regulatory Action.....	18
14	Fees for Wholesale Dealer’s Licence (WDA(H)) applications .....	18
15	Further information .....	19
16	Glossary of legislation .....	20
	Appendix 1 Requirements for brokers .....	21
	Appendix 2 A description of the conditions of a Wholesale Dealer’s Licence (WDA(H)) .....	23

# 1 Introduction

- 1.1 This Guidance Note has been published to assist applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration and outline the key obligations for maintaining the licence/registration. The Guidance Note provides a basic overview of these requirements. For more in-depth guidance, please refer to the Rules and Guidance for Pharmaceutical and Distributors ("The Green Guide") available from Pharmaceutical Press: <http://www.pharmpress.com/>.
- 1.2 Reference to a 'Wholesale Dealer's Licence' in this Guidance Note means a licence granted pursuant to regulation 18 of the Human Medicines Regulations 2012 [SI 2012/1916]. A 'Wholesale Distribution Authorisation' has a corresponding meaning.
- 1.3 The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. Recognised globally as an authority in its field, the agency plays a leading role in protecting and improving public health and supports innovation through scientific research and development. Pharmaceutical manufacturers and distributors operating in the UK marketplace are subject to a system of licensing and inspection, which ensures that licensed medicinal products conform to internationally agreed standards, and that those medicines are manufactured, stored and distributed in compliance with the required regulatory standards.
- 1.4 Before a medicine can be marketed or sold in the UK, a number of licences are required. The product itself must have a licence called a 'marketing authorisation' (formerly a 'product licence') unless an exemption applies. In addition, the companies that are involved in all stages of the manufacture and distribution of the product need to have the relevant licence for the activity in question (Manufacturer's and/or Wholesale Dealer's Licences).
- 1.5 In the UK the regulation of medicines on the UK market is undertaken by MHRA in accordance with the Human Medicines Regulations 2012 [2012/1916].
- 1.6 The manufacture and distribution of veterinary medicinal products for animal use is subject to separate legislation. Further advice should be sought from the Veterinary Medicines Directorate (VMD) of DEFRA.
- 1.7 The Licensing Authority, for the purposes of the Human Medicines Regulations 2012 and this Guidance Note refers to the Ministers<sup>1</sup> where the Ministers means the Secretary of State; and the Minister for Health, Social Services and Public Safety, designated by the Regulations, acting either alone or jointly. MHRA is the Government body set up to discharge the responsibilities of the Licensing Authority, under powers delegated by those Ministers.

---

<sup>1</sup> The Secretary of State and the Minister for Health, Social Services and Public Safety.

## **2 Wholesale dealing or distribution**

- 2.1 Medicinal products which are medicines for human use are subject to the provisions of the Human Medicines Regulations 2012. This includes unlicensed medicinal products commonly referred to as “specials”.
- 2.2 It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the UK through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.
- 2.3 The Human Medicines Regulations 2012 defines wholesale distribution of medicinal products as: “selling or supplying it, or procuring or holding it or exporting it for the purposes of sale or supply to a person who receives it for a purpose. Those purposes are selling or supplying the product or administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person.”
- 2.4 The holder of a Wholesale Dealer’s Licence must fulfil certain obligations and conditions. See Section 5 and Appendix 2.

## **3 Brokering**

- 3.1 The distribution network for medicinal products may involve operators who are not necessarily authorised wholesale dealers. To ensure the reliability of the supply chain, medicines legislation includes brokering of medicinal products and is defined in the Human Medicines Regulations 2012 as follows:

“All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.”
- 3.2 To accord with the Human Medicines Regulations 2012, brokers of medicinal products are required to register their activities with the MHRA.
- 3.3 Brokers can negotiate between the manufacturer and a wholesaler, or one wholesaler and another wholesaler, or the manufacturer or wholesale dealer with a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale or a person who may lawfully administer those products.
- 3.4 Brokers do not procure, supply or hold medicines. The definition of brokering medicinal products specifically excludes the activity of wholesale dealing. Wholesale dealing and brokering of medicinal products are separate activities therefore wholesale dealers who wish to broker will require a separate registration.
- 3.5 Brokers must adhere to certain requirements of the registration including compliance with chapter 10 of Good Distribution Practice:

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF>

- 3.6 In addition, brokers may only broker medicinal products that are the subject of a marketing authorisation granted by the licensing authority or by a competent authority of an EEA state. Further requirements of a broker registration can be found in Appendix 1 of this Guidance Note and regulations 45A-L<sup>2</sup> of the Human Medicines Regulations 2012: <http://www.legislation.gov.uk/ukxi/2012/1916/contents/made>

## 4 How to register as a Broker

- 4.1 Brokers of medicinal products based in the UK must register their activities with MHRA. Applicants for a new broker registration or existing brokers wishing to vary their registration or submit an annual compliance report should apply for registration as a broker on [MHRA Submissions](https://mhrabpm.appiancloud.com/suite/) <https://mhrabpm.appiancloud.com/suite/>
- 4.2 The relevant fee will be required upon application. A schedule of the current fees is available on MHRA's website: <https://www.gov.uk/guidance/medicines-register-as-a-broker>
- 4.3 The application procedure will include:
- making an application for registration;
  - assessment by the MHRA of the application;
  - providing specific evidence to check bona fides;
  - advising an applicant of the decision.
- 4.4 UK brokers may be subject to inspection at their registered premises. This will be under a risk-based inspection programme. Once registered, MHRA will enter the registration information on a publicly accessible UK broker register: <https://www.gov.uk/government/publications/register-of-brokers-authorised-to-deal-in-human-medicines>
- 4.5 Where a registered broker changes details of their registration which might affect compliance with the requirements of the legislation, a variation to the registration should be submitted without unnecessary delay. In addition, registered brokers are required to submit an annual compliance report to declare compliance with the requirements of the registration and provide details of the systems in place.

## 5 Persons requiring a Wholesale Dealer's Licence (WDA(H))

- 5.1 Persons operating from the UK require a Wholesale Dealer's Licence (WDA(H)) if, in the course of their business, they are engaged in:
- importing a medicinal product from an approved country for import into Great Britain for the purposes of distributing a medicinal product by way of wholesale dealing, or possessing a medicinal product for the purpose of such distribution;

---

<sup>2</sup> Inserted by The Human Medicines (Amendment) Regulations 2013 [SI 2013/1855]  
<http://www.legislation.gov.uk/ukxi/2013/1855/regulation/16/made>

- procuring, holding, supplying or selling medicinal products for human use sourced in the UK or an approved country for import to anyone other than members of the public or exporting it for the purposes of sale or supply;
- supplying a listed Northern Ireland MHRA Authorised Route (NIMAR) medicinal product from Great Britain to Northern Ireland.

This includes virtual operations where no physical handling of the products takes place.

5.2 The need for a Wholesale Dealer's Licence does not apply:

- (a)(i) to anything done in relation to a medicinal product by the holder of a Manufacturer's Licence in respect of that product,
- (ii) where the product concerned is an investigational medicinal product, or
- (iii) if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source; and
- (b) is subject to regulation 19 Exemptions from requirement for Wholesale Dealer's Licence.
- (1) to the sale or offer for sale of a medicinal product by way of wholesale dealing, or possession for the purpose of such sale or offer where paragraph (2) applies and the person selling or offering the product for sale is—
  - [(a) the holder of—
    - (i) in the case of a product for sale or supply in Great Britain [(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)], a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation") which relates to the product, or
    - (ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation") which relates to the product,
 including a holder of an authorisation who manufactured or assembled the product; or]
  - (b) a person who is not the holder of an authorisation in relation to the product but manufactured or assembled the product [in the United Kingdom] to the order of a person who is the holder of an authorisation relating to the product.
- to a person who in connection with the importation of a medicinal product-
  - (a) provides facilities solely for transporting the product; or
  - (b) acting as an import agent, handles the product where the product is imported solely to the order of another person who intends to sell the product or offer it for sale by way of wholesale dealing or to distribute it in any other way.
- in connection with the distribution by way of wholesale dealing of a medicinal product to be used for vaccination or immunisation against coronavirus or influenza virus under the relevant arrangements.
- in connection with the distribution by way of wholesale dealing of a medicinal product to be supplied or administered in accordance with a protocol of the type mentioned in regulation 247.
- to a person ("P") who imports a medicinal product into Great Britain from an approved country for import for administration to P or to any other person who is a member of P's household.
- Paragraph (2) (mentioned above in 5.2 (1)), This paragraph applies if—

- (a) until the sale, the medicinal product has been kept on the premises of the person who manufactured or assembled the product (in this regulation referred to as “authorised premises”); and
- (b) those premises are premises authorised for use for manufacture or assembly by that person's manufacturer's licence.

5.3 There are several licence categories for which an application for a wholesale dealers' licence can be submitted, these include:

<b>1 Categories Pertaining to the authorisation status of Medicinal Products</b>
1.1 - With “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
1.2 - Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in Great Britain and intended for the UK market.
1.3 - Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market
1.4 - With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market
<b>2 Categories Pertaining to Authorised Wholesale Distribution Operations</b>
2.1 Procurement
2.2 Holding
2.3 Supply
2.4 Export
2.5 Other Activities
2.6 Products imported from approved country for import
2.6a Products Certified under Article 51 of Directive 2001/83/EC
2.6b Products not certified under Article 51 of Directive 2001/83/EC
<b>3 Categories Pertaining to Medicinal Products with Additional Requirements</b>
3.2 Medicinal gases
3.3 Cold chain products (requiring low temperature handling)
3.1.1 Narcotic or psychotropic products
3.1.2 Medicinal products derived from blood
3.1.3 Immunological medicinal products
3.1.4 Radiopharmaceutical (including radionuclide kits)
3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
<b>4 Categories of Products Handled at this Site</b>
4.1 Prescription Only Medicines (POM)
4.2 General Sales List
4.3 General Sales List Only
4.4 Pharmacy
4.5 Traditional Herbal Medicinal Products (THMP)
4.6 Homeopathic products



- 5.4 The categories pertaining to authorised wholesale distribution operations are defined as follows in the Human Medicines Regulations 2012:

*Selling:*

References to selling by retail, or to retail sale, are references to selling a product to a person who buys it otherwise than for a purpose specified in regulation [18(5)].

*Supplying:*

References to supplying anything in circumstances corresponding to retail sale are references to supplying it, otherwise than by way of sale, to a person who receives it otherwise than for a purpose specified in regulation [18(5)].

*Exporting:*

Export, or attempt to export, from the United Kingdom, whether by land, sea or air.

## **6 How to apply for a Wholesale Dealer's Licence (WDA(H))**

- 6.1 Applicants for a new Wholesale Dealer's Licence (WDA(H)) or existing licence holders wishing to vary their licence should apply using the MHRA Process Licensing Portal accessible via the MHRA website:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Licenceapplicationforms/Wholesaledealerslicencesapplicationforms/index.htm>

<https://pclportal.mhra.gov.uk/>

- 6.2 The Licensing Authority will only issue a Wholesale Dealer's Licence when it is satisfied, following an inspection of the site(s), that the information contained in the application is accurate and in compliance with the requirements of the legislation.
- 6.3 When appropriate, the Licensing Authority may refuse to grant a Wholesale Dealer's Licence or may grant a Wholesale Dealer's Licence otherwise than as applied for. In such cases the Licensing Authority will notify the applicant of its proposals. The notification will set out the reasons for its proposals and give the applicant a period of not less than 28 days to respond.

## **7 Application requirements:**

- 7.1 New applicants for a wholesale dealer's licence are expected to ensure that they are inspection ready at the point of application. As a result, applicants must ensure that the necessary procedures are in place for a full review of the proposed wholesale operation, this includes:

- A written document that describes the company's proposed business model detailing both product and fiscal flows.

- Details of the premises and equipment involved in the wholesale operation (including details of ambient and cold chain storage facilities, transport arrangements, computerised systems and any business contingency plans).
- Details of any outsourced activities and copies of any associated quality/technical agreements held for such arrangements.
- Having an approved quality management system in place (including the Quality Manual, Policies, Standard Operating Procedures and relevant Forms), including any index.
- A detailed list of the risk assessments that have been carried out.
- Having detailed training records and job descriptions for all persons involved in the proposed wholesale operation, especially that of the Responsible Person.
- Being able to demonstrate that a temperature mapping exercise has been conducted of the proposed wholesale area with a clear methodology.
- Having a list of qualified prospective suppliers and customers.
- Being able to demonstrate a clear schedule and methodology for self-inspections.
- Having records of management review meetings
- Being able to provide evidence of transport validation.

7.2 New applicants for a Wholesale Dealer's Licence should familiarise themselves with the general best practice for inspections, please refer to the link below for guidance:

Link to Good Distribution Practice Inspectorate blog post for best practice on inspection <https://mhrainspectorate.blog.gov.uk/category/good-distribution-practice/>

## **8 Wholesale dealer's obligations**

- 8.1 The holder of a Wholesale Dealer's Licence (WDA(H)) must comply with the conditions set out in regulations 43 – 45AB of the Human Medicines Regulations 2012. These include compliance with Good Distribution Practice.
- 8.2 See Appendix 2 for a description of the conditions of the licence.

## **9 Responsible Person**

- 9.1 Regulation 45 of the Human Medicines Regulations 2012, as amended, requires that all licensed wholesale dealers should have at their disposal at least one person available as the Responsible Person (RP). The Responsible Person should have appropriate competence and experience, as well as knowledge of and training in Good Distribution Practice.
- 9.2 A Responsible Person Gold Standard was approved in April 2014. This sets out an industry-agreed framework that identifies the skills required in four competency areas and includes not only traditional qualifications and technical requirements, but also the behavioural skills necessary to do the job to a high standard. The Gold Standard is a competency framework, or role profile, and should be used by:
- the Licence Holder to assist in selection and induction of the RP;

- the RP in identifying the extent to which he/she fulfils the role and in compiling a training programme;
- the prospective RP in planning their learning and experience to prepare for a future role.

<https://www.cogentskills.solutions/standards/the-role-of-responsible-person-in-good-distribution-practice/>

- 9.3 The RP is responsible for ensuring that the conditions under which the licence was granted have been, and are being, complied with; and ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of the marketing authorisations applicable to those products;
- in the case of a licence holder in Great Britain, the UK marketing authorisations, certificates of registration or traditional herbal registrations and
  - in the case of a licence holder in Northern Ireland, the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations.

The responsibilities of an RP include:

- ensuring that a quality management system is implemented and maintained;
- focusing on the management of authorised activities and the accuracy and quality of records;
- ensuring that initial and continuous training programmes are implemented and maintained;
- coordinating and promptly performing any recall operations for medicinal products;
- ensuring that relevant customer complaints are dealt with effectively;
- ensuring that suppliers and customers are approved;
- approving any subcontracted activities that may impact on Good Distribution Practice;
- ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;
- keeping appropriate records of any delegated duties;
- deciding on the final disposition of returned, rejected, recalled, or falsified products;
- approving any returns to saleable stock;
- ensuring that any additional requirements imposed on certain products by national law are adhered to.

- 9.4 The Responsible Person should fulfil their responsibilities personally and should be continuously contactable. The RP should be resident in the UK and proof of identity and address is required as part of the application process.

Where there is more than one RP named on the licence, each is expected to take full responsibility for the role, within the scope of their responsibilities as defined in their job description and agreed with the licence holder. It should be clear within the quality system which of the RPs is primarily accountable for the responsibilities described in Good Distribution Practice; responsibilities may be allocated either by function (e.g.

oversight of the training programme) or where a company operates more than one site it may be possible to allocate responsibilities by site, providing full oversight of activities at a particular site or sites.

- 9.5 If the RP cannot demonstrate the required experience and knowledge or is not adequately carrying out those duties, the Licensing Authority may compulsorily vary the licence to remove the RP or refuse acceptance of the RP on that licence application. These actions may be extended to any other licence on which the RP is named.
- 9.6 The RP does not have to be an employee of the licence holder but must be continuously contactable. Where the RP is not an employee, there should be a written contract between the licence holder and the RP specifying responsibilities, duties, authority and time on site. Where a contract RP provides services from within a contracting company, the contract should be with the specific RP and not the contracting company.
- 9.7 The RP should have access to relevant pharmaceutical and technical knowledge and advice when it is required, and have personal knowledge of:
- the relevant provisions of the Human Medicines Regulations 2012 [SI 2012/1916] and amendments;
  - the relevant legislation in the intended market the organisation is supplying to;
  - the guidelines on Good Distribution Practice;
  - the conditions of the Wholesale Dealer's Licence for which nominated;
  - the products traded under the licence and the conditions necessary for their safe storage and distribution;
  - the categories of persons to whom products may be distributed.

The RP should also maintain their competence in Good Distribution Practice through regular training and keep records as evidence.

- 9.8 The RP must demonstrate they have at least 1 year's practical experience of the activities authorised on the licence, i.e. procuring, holding, supplying or exporting. The RP must have obtained the technical knowledge of how to qualify suppliers, identify medicinal products, understand storage conditions and temperature control, qualify customers and how to transport medicinal products.
- 9.9 The RP should have at least 1 year's experience in maintaining a quality management system appropriate to the licence for which nominated.

The RP should be able to demonstrate they have completed relevant training in Good Distribution Practice.

- 9.10 To carry out their responsibilities, the RP should:
- have a clear reporting line to the licence holder;
  - have the defined authority, resources and responsibility needed to fulfil their duties;
  - have access to all areas, sites, stores, staff and records relating to the licensable activities being carried out;

- demonstrate regular review and monitoring of all such areas, sites and staff etc.;
- have delegated arrangements whereby the RP receives written reports that such delegated actions have been carried out on behalf of the RP in compliance with standard operating procedures and Good Distribution Practice. The RP remains responsible and should have demonstrable oversight of delegated duties;
- focus on the management of licensable activities, the accuracy and quality of records, compliance with standard operating procedures and Good Distribution Practice, the quality of handling and storage equipment and facilities, and the standards achieved;
- keep appropriate records relating to the discharge of the RP responsibilities.

9.11 Where the licence covers a number of sites, the RP may have a nominated deputy with appropriate reporting and delegating arrangements. However, the RP should be able to demonstrate to the Licensing Authority that the necessary controls and checks are in place. The term “Deputy RP” is not legally recognised but is often used. Only the Responsible Person(s) named on a wholesale dealer’s licence have legal responsibility for the organisation’s compliance and remain responsible for any duties that have been delegated.

9.12 The licence holder should ensure that there is a process for receiving advice and comment from the RP and recording the consequent action taken as may be necessary.

9.13 Should it prove impossible to resolve a disagreement between the licence holder and the RP, the Licensing Authority should be consulted.

9.14 Whilst a joint referral is clearly to be preferred, either party may approach the Licensing Authority independently. If an RP finds difficulty in performing statutory responsibilities or the activities being carried out under the licence, the Licensing Authority should be consulted in strict confidence.

## **10 Responsible Person (Import)**

10.1 Where the licence holder in Great Britain imports a licensed medicinal product from an approved country for import under a wholesale dealer’s licence, there is a requirement for a Responsible Person (Import) (RPi).

10.2 A RPi must:

- carry out the functions under section 9.0 (above);
- ensure that there is appropriate evidence to confirm that each production batch of a medicine imported from an approved country for import under the licence has been certified as provided for in article 51 of the 2001/83/EC Directive, or such equivalent certification procedure as applies in the approved country for import;
- Ensure that each production batch of a medicinal product that is subject to the batch testing condition and that is imported into Great Britain from an approved country for import has been certified as being in conformity with the approved specifications in the UK marketing authorisation by
  - (i) the appropriate authority, or

- (ii) Where the batch testing exemption applies, a laboratory in a country that has an agreement with the United Kingdom to the effect that the appropriate authority will recognise that certificate in place of the appropriate authority's own examination.

10.3 The requirement for a RPi does not apply where an unlicensed medicinal product (unlicensed medicine both in the UK and in the approved country for import) is imported from an approved country for import for the sole purpose of distribution by way of wholesale dealing as a special medicinal product, or for the sole purpose of wholesale distribution of that product to a person in a country other than an approved country for import.

## 11 Inspection

11.1 The Good Distribution Practice Inspectors carry out regular and repeated inspections of wholesale distribution sites. Inspection enables the Licensing Authority to confirm that licence holders are complying with the conditions of their licence, with the provisions of the Human Medicines Regulations 2012 and with the requirements of Good Distribution Practice.

11.2 Amongst other things, Good Distribution Practice Inspectors are empowered to:

- inspect the premises, organised arrangements and procedures used in the storage and distribution of medicinal products;
- interview key personnel named on licences;
- take samples;
- require production and examine any documentation or records relating to the manufacture, assembly, storage and distribution of medicinal products. It is a requirement of UK national legislation that licence holders shall make their premises available for inspections by the Licensing Authority at any reasonable time, regardless of whether prior notice has been given.

11.3 A fee is charged for these inspections. See Section 12.

11.4 The major stages of the inspection process are:

- the introductory or opening meeting;
- the detailed inspection;
- the summary or closing meeting.

11.5 The purpose of the introductory or opening meeting is for the Inspector to meet with the appropriate key personnel from the company to discuss the arrangements for the inspection. The Inspector would typically confirm the nature of the business, premises and security arrangements, areas to be visited and any documentation which may be required.

11.6 The purpose of the detailed site inspection is to determine the degree of conformity of the operations to requirements of good practice and to assess compliance with the terms and conditions of licences issued under the appropriate legislation or with details submitted in support of an application for a licence. The inspection will typically involve visits to goods inward, storage areas (including ambient and refrigerated),

returns area, interviews with key personnel and review of stock movement and quality system documentation including product recalls. Any observations, recommendations and deficiencies noted during the inspection would normally be discussed with the company representatives at the time.

- 11.7 During inspections of manufacturing and wholesale operations, samples of starting materials, work in progress and finished products may be taken for testing if an Inspector considers that this might assist in the detection of quality deficiencies. Occasionally, samples may be taken when these cannot be obtained from other sources, for routine surveillance purposes.
- 11.8 The purpose of the summary or closing meeting is for the Inspector to provide the company with a verbal summary of the inspection findings and to allow the company to correct at this stage any misconceptions. The Inspector would typically summarise the definition and classification of deficiencies they propose to report (see below) and the company are encouraged to give an undertaking to resolve the deficiencies and to agree a provisional timetable for corrective action. The Inspector would also describe the arrangements for the formal notification of the deficiencies to the company (the post-inspection letter) and what is expected as a response.
- 11.9 Deficiencies are classified as follows:
- *Critical Deficiency:*  
Any departure from Good Distribution Practice resulting in a medicinal product causing a significant risk to the patient and public health. This includes an activity increasing the risk of falsified medicines reaching the patients.  
A combination of a number of major deficiencies that indicates a serious systems failure.  
An example of a critical deficiency could be:  
Purchase from or supply of medicinal products to a non-authorized person;  
Storage of products requiring refrigeration at ambient temperatures;  
Rejected or recalled products found in sellable stock.
  - *Major Deficiency:*  
A non-critical deficiency:  
which indicates a major deviation from Good Distribution Practice;  
or which has caused or may cause a medicinal product not to comply with its marketing authorisation in particular its storage and transport conditions;  
or which indicates a major deviation from the terms and provisions of the wholesale distribution authorisation;  
or a combination of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency.
  - *Other Deficiency:*  
A deficiency which cannot be classified as either critical or major, but which indicates a departure from Guidelines on Good Distribution Practice.
- 11.10 The choice of company representatives at the meeting is primarily for the company to decide, but should normally include the senior staff who were present during the inspection and the RP.

- 11.11 Following an inspection, the Good Distribution Practice Inspector prepares a report of their findings. A letter is sent to the licence applicant or holder noting any deficiencies found and asking for proposals to remedy them. In the most serious cases the report is referred to the Licensing Authority for considering more formal action (see 6.3). Where the licence is granted, subsequent inspections are based on a risk assessment. The inspector will use the inspection outputs along with a number of other factors to identify a risk rating for the site which, will in turn, equate to a future inspection frequency.

## 12 Falsified and diverted medicines

### Falsified medicines

- 12.1 A “falsified medicinal product” means any medicinal product with a false representation of:
- (a) its identity, including its packaging and labelling, its name or its composition (other than any unintentional quality defect) as regards any of its ingredients including excipients and the strength of those ingredients;
  - (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
  - (c) its history, including the records and documents relating to the distribution channels used.
- 12.2 The supply of falsified medicines is a global phenomenon and one which MHRA takes very seriously. Falsified medicines represent a threat to the legitimate UK supply chain and to patient safety. They are fraudulent and may be deliberately misrepresented with respect to identity, composition and/or source. Falsification can apply to both innovator and generic products, prescription and self-medication, as well as to traditional herbal remedies. Falsified medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients, and may even contain harmful or poisonous substances. The supply and distribution of medicines is tightly controlled.
- 12.3 All licensed wholesalers must comply with Good Distribution Practice and there exist strict licensing and regulatory requirements in UK domestic legislation to safeguard patients against potential hazards arising from poor distribution practices: for example, purchasing suspect or falsified products, failing to establish the “bona fides” of suppliers and purchasers, inadequate record keeping, and so on.
- 12.4 Section 6.4 of Good Distribution Practice is of principal importance to wholesale dealers. This states that:
- “Wholesale distributors must immediately inform the competent authority and the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified.



A procedure should be in place to this effect. It should be recorded with all the original details and investigated.

Any falsified medicinal products found in the supply chain should immediately be physically segregated and stored in a dedicated area away from all other medicinal products. All relevant activities in relation to such products should be documented and records retained.”

12.5 Wholesale dealers in particular should maintain a high level of vigilance against the procurement or supply of potentially falsified product. Such product may be offered for sale below the established market price so rigorous checks should be made on the bona fides of the supplier and the origin of the product. It is known that some wholesalers are themselves developing good practice strategies – such as conducting rigorous physical inspections of packs when grey market purchases are made – and this is encouraged.

12.6 Any suspicious activity should be reported to:

Email: [thebureau@mhra.gov.uk](mailto:thebureau@mhra.gov.uk)  
Telephone: +44 (0)20 3080 6330

12.7 To report suspected falsified medicines or medical devices:

Email: [fakemeds@mhra.gov.uk](mailto:fakemeds@mhra.gov.uk)  
Website: <http://www.gov.uk/mhra>  
Telephone: +44 (0)20 3080 6701

### **Diverted medicines**

12.8 Diversion is the term used for the fraudulent activity where medicines destined for non-EU markets are re-imported and are placed back on to the market at a higher price.

12.9 The diversion of medicines involves medicinal products being offered at preferential prices and exported to specific markets (normally third world countries). Diversion occurs when unscrupulous traders, on receipt of the medicines, re-export the products with the consequence that patients, for whom these preferentially-priced medicines were intended, are denied access to them. Such products re-appearing on the EU or UK markets are then known as “diverted” from their intended market. This represents not only a corrupt diversion for profit, but such activity also poses the risk of inappropriate or unlicensed use<sup>3</sup>, and the risk that the product may also be compromised due to poor storage and transportation.

12.10 As with counterfeit products, wholesale dealers in particular should maintain a high level of vigilance against the procurement or supply of potentially diverted product.

---

<sup>3</sup> REGULATION (EU) 2016/793 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines  
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0793&from=en>

Diverted products may be offered for sale below the established market value, therefore appropriate checks should be made on the bona fides of the supplier and the origin of the product should be ascertained.

## **13 Regulatory Action**

- 13.1 The Licensing Authority will take regulatory action where breaches of legislation are identified; this may take the form of adverse licensing action e.g. compulsorily making a variation to an existing licence/registration, suspension or revocation of a licence/registration and/or the instigation of criminal proceedings.
- 13.2 Where poor compliance is identified which does not meet the threshold for consideration of adverse regulatory action, a compliance escalation process may be implemented. The process is managed by the Compliance Management Team (CMT) and refocuses companies towards a state of compliance, without the need for regulatory action.

## **14 Fees for Wholesale Dealer's Licence (WDA(H)) applications**

- 14.1 The Medicines Act 1971 introduced provisions for the payment of fees for licences, certificates and inspections. The current fees legislation for human medicinal products is contained in The Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190 No. 190).
- 14.2 Fees are currently payable for the following:
- new applications for a WDA(H);
  - variations to an existing WDA(H);
  - inspections;
  - change of ownership.
- 14.3 An annual service charge is also payable during the currency of a licence.
- 14.4 A schedule of the current fees is available on MHRA's website:  
<https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees#contents>
- 14.5 When MHRA plans to make changes to the amount or frequency of fees, licence holders are consulted and given the opportunity to comment on MHRA's proposals which can be found on MHRA's website.

## 15 Further information

15.1 More detailed information on wholesaling and brokering including extracts from UK medicines legislation, and notes on duties of the RP can be found in *Rules and Guidance for Pharmaceutical and Distributors* ("The Green Guide") available from Pharmaceutical Press, <http://www.pharmpress.com/>

15.2 Copies of relevant UK statutory instruments are also available from The Stationery Office, <https://www.tso.co.uk/> and Legislation.gov.uk: <http://www.legislation.gov.uk/>

15.3 Copies of the following MHRA Guidance are available on MHRA's website:

MHRA Guidance Note 5: Notes for applicants and holders of a Manufacturer's Licence

MHRA Guidance Note 6: Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration

MHRA Guidance Note 8: A guide to what is a medicinal product

MHRA Guidance Note 14: The supply of unlicensed medicinal products ("specials")

MHRA Guidance: The Blue Guide - Advertising and promotion of medicines in the UK

MHRA Guidance: Best Practice Guidance on the labelling and packaging of medicines

## 16 Glossary of legislation

### UK legislation

#### **The Human Medicines Regulations 2012 (SI 2012/1916)**

*Replaces nearly all UK medicines legislation – most of the Medicines Act 1968 and over 200 statutory instruments. The Regulations set out a comprehensive regime for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance.*

#### **The Human Medicines (Amendment) Regulations 2013 (SI 2013/1855)**

*The majority of provisions in these amending Regulations introduce new provisions into the 2012 Regulations in relation to brokers, active substances and the sale of medicinal products at a distance in order to implement Directive 2011/62/EU as regards the prevention of the entry into the legal supply chain of falsified medicinal products.*

#### **The Medicines (Products for Human Use) (Fees) Regulations 2016 (SI 2016/190)**

*These Regulations make provision for the fees payable under the Medicines Act 1971 in respect of marketing authorisations, licences and certificates relating to medicinal products for human use.*

#### **The Medicines for Human Use (Clinical Trials) Regulations (SI 2004/1031)**

*These Regulations implement Directive 2001/20/EC on the approximation of laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.*

#### **The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations (SI 2003/1680)**

*Regulates the importation and marketing of unlicensed medicinal products for human use in order to minimise the risk of the transmission of Transmissible Spongiform Encephalopathies via those products.*

## APPENDIX 1 - Requirements for brokers

A person may not broker a medicinal product unless that product is covered by an authorisation granted under Regulation (EC) No 726/2004 or by the Licensing authority, or by a competent authority of a member State and that person is validly registered as a broker with the licensing authority or a competent authority of a member state.

A broker is not validly registered if the broker's permanent address is not entered into a register of brokers kept by the Licensing authority or the registration is suspended or the broker has notified the competent authority to remove them from the register.

Brokers must satisfy all the conditions of brokering and:

- have a permanent address in the UK;
- have an emergency plan which ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the manufacturer or marketing authorisation holder for the medicinal product concerned;
- keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products brokered at least the following information:
  - date on which the sale or purchase of the product is brokered;
  - name of the medicinal product;
  - quantity brokered;
  - name and address of the supplier or consignee, as appropriate;
  - batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC (where the sale or supply of the medicinal product is in Northern Ireland);
- keep the documents or records available to the licensing authorities, for inspection purposes, for a period of five years;
- comply with the principles and guidelines of Good Distribution Practice for medicinal products as laid down in Article 84 of Directive 2001/83/EC;
- maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

Where the address at which the plan or records necessary to comply with the provisions of brokering are kept is different from the address notified in accordance with the application, the broker must ensure that the plan or records are kept at an

address in the UK and inform the licensing authority of the address at which the plan or records are kept.

The broker must provide such information as may be requested by the MHRA concerning the type and quantity of medicinal products brokered within the period specified by the licensing authority MHRA.

The broker must take all reasonable precautions and exercise all due diligence to ensure that any information provided by that broker to the MHRA is not false or misleading.

For the purposes of enabling the MHRA to determine whether there are grounds for suspending, revoking or varying the registration, the broker must permit a person authorised in writing by the MHRA, on production of identification, to carry out any inspection, or to take any copies, which an inspector may carry out or take under the provisions of the Human Medicines Regulations 2012 [SI 2012/1916].

## APPENDIX 2 - A description of the conditions of a Wholesale Dealer's Licence

The Regulations require that the licence holder shall:

- comply with the guidelines on Good Distribution Practice;<sup>4</sup>
- ensure, within the limits of their responsibility as a distributor of medicinal products, the appropriate and continued supply of such medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstances corresponding to retail sale, so that the needs of patients in the UK are met;
- provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products under the licence as are necessary to maintain the quality of, and ensure proper distribution of the medicinal products;
- inform the Licensing Authority of any proposed structural alteration to, or discontinued use of, premises to which the licence relates or premises which have been approved by the Licensing Authority;
- inform the Licensing Authority of any change to the Responsible Person.

The holder of a Wholesale Dealer's Licence shall not sell or offer for sale or supply any medicinal product in Great Britain unless there is a UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration for the time being in force in respect of that product. In the case of a product for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration ("an authorisation") for the time being in force in respect of that product; and the sale or offer for sale is in accordance with the provisions of that authorisation. This restriction on the holder of a Wholesale Dealer's Licence shall not apply to:

- the sale or offer for sale of a special medicinal product; and
- the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration by virtue of legislation adopted by that State under Article 5(1) of the 2001 Directive; or
- the sale or supply, or offer for sale or supply, of an unauthorised medicinal product where the Secretary of State has temporarily authorised the distribution of the product under regulation 174 of the Regulations.

The holder of a Wholesale Dealer's Licence shall:

- keep such documents relating to the sale of medicinal products to which their licence relates which may facilitate the withdrawal or recall from sale of medicinal products in accordance with an emergency plan referred to below;

---

<sup>4</sup> Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF>

- have in place an emergency plan which will ensure effective implementation of the recall from the market of any relevant medicinal products where such recall is:
  - ordered by the Licensing Authority or by the competent authority of any EEA State, or
  - carried out in co-operation with the manufacturer of, or the holder of the marketing authorisation for, the product in question;
- keep records in relation to the receipt, dispatch or brokering of medicinal products, of the date of receipt, the date of despatch, the date of brokering, the name of the medicinal product, the quantity of the product received, dispatched or brokered, the name and address of the person from whom the products were received or to whom they are dispatched, and the batch number of medicinal products bearing safety features referred to in point (o) of Article 54<sup>5</sup> of the 2001 Directive.

Where the holder of a Wholesale Dealer's Licence in Northern Ireland imports from another EEA State for which they are not the holder of the marketing authorisation, Article 126a authorisation, certificate of registration or a traditional herbal registration of the product, then they shall notify the holder of that authorisation of their intention to import that product. In the case where the product is the subject of a marketing authorisation granted under Regulation (EC) No 726/2004, the holder of the Wholesale Dealer's Licence shall notify the EMA or for any other authorisation they shall notify the Licensing Authority. In both cases they will be required to pay a fee to the EMA in accordance with Article 76(4)<sup>6</sup> of the 2001 Directive or the Licensing Authority as the case may be, in accordance with the Fees Regulations. These requirements will not apply in relation to the wholesale distribution of medicinal products to a person in a non-EEA country.

The licence holder, for the purposes of enabling the Licensing Authority to determine whether there are grounds for suspending, revoking or varying the licence, must permit a person authorised in writing by the Licensing Authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement) of the Regulations.

The holder of a Wholesale Dealer's Licence must verify that any medicinal products they receive which are required by Article 54a<sup>7</sup> of the Directive to bear safety features are not falsified. This does not apply in relation to the distribution of medicinal products received from a third country by a person for supply to a person in a third country. Any verification is carried out by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted under Article 54a(2) of the 2001 Directive.

The licence holder must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

---

<sup>5</sup> Point (o) of Article 54a was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

<sup>6</sup> Article 76(4) was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

<sup>7</sup> Article 54a was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).



The licence holder must also immediately inform the Licensing Authority and, where applicable, the marketing authorisation holder, of medicinal products which the licence holder receives or is offered which the licence holder knows or suspects, or has reasonable grounds for knowing or suspecting, to be falsified.

Where the medicinal product is obtained through brokering, the licence holder must verify that the broker involved fulfils the requirements set out in the Regulations.

The licence holder must not obtain supplies of medicinal products from anyone except the holder of a Manufacturer's Licence or Wholesale Dealer's Licence in relation to products of that description or the person who holds an authorisation granted by another EEA State authorising the manufacture of products of the description or their distribution by way of wholesale dealing. The supply must be in accordance with the principles and guidelines of Good Distribution Practice. This does not apply in relation to the distribution of medicinal products directly received from a non-EEA country but not imported into the EU.

From 28 October 2013 where the medicinal product is directly received from a non-EEA country for export to a non-EEA country, the licensed wholesale dealer must check that the supplier of the medicinal product in the exporting non-EEA country is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in that country.

The holder of a Wholesale Dealer's Licence must verify that the wholesale dealer who supplies the product complies with the principles and guidelines of Good Distribution Practices; or the manufacturer or importer who supplies the product holds a manufacturing authorisation.

The holder of a Wholesale Dealer's Licence may distribute medicinal products by way of wholesale dealing only to the holder of a Wholesale Dealer's Licence relating to those products, the holder of an authorisation granted by the competent authority of another EEA State authorising the supply of those products by way of wholesale dealing, a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale; or a person who may lawfully administer those products. This does not apply in relation to medicinal products which are distributed by way of wholesale dealing to a person in a non-EEA country.

From 28 October 2013, where the medicinal product is supplied directly to persons in a non-EEA country the licensed wholesale dealer must check that the person that receives it is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the non-EEA country concerned.

Where any medicinal product is supplied to any person who may lawfully sell those products by retail or who may lawfully supply them in circumstances corresponding to retail sale, the licence holder shall enclose with the product a document which makes it possible to ascertain:

- the date on which the supply took place;
- the name and pharmaceutical form of the product supplied;

- the quantity of product supplied;
- the name and address of the licence holder; and
- the batch number of the medicinal products bearing the safety features referred to in point (o) of Article 54 of the 2001 Directive (in the case of a licence holder in Northern Ireland).

The holder of a Wholesale Dealer's Licence shall keep a record of the information supplied where any medicinal product is supplied to any person who may lawfully sell those products by retail or who may lawfully supply them in circumstance corresponding to retail sale for a minimum period of five years after the date on which it is supplied and ensure, during that period, that that record is available to the Licensing Authority for inspection.

The Wholesale Dealer's Licence holder shall at all times have at their disposal the services of a responsible person who, in the opinion of the Licensing Authority has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate for performing the functions of responsible person; and has experience in those procedures and activities which is adequate for those purposes.

The functions of the responsible person shall be to ensure, in relation to medicinal products, that the conditions under which the licence has been granted have been, and are being, complied with and the quality of medicinal products which are being handled by the Wholesale Dealer's Licence holder are being maintained in accordance with the requirements of the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applicable to those products.

The standard provisions for Wholesale Dealer's Licences, that is, those provisions which may be included in all licences unless the licence specifically provides otherwise, insofar as those licences relate to relevant medicinal products, shall be those provisions set out in Part 4 of Schedule 4 of the Regulations.

The licence holder shall not use any premises for the purpose of the handling, storage or distribution of relevant medicinal products other than those specified in their licence or notified to the Licensing Authority by them and approved by the Licensing Authority.

The licence holder shall provide such information as may be requested by the Licensing Authority concerning the type and quantity of any relevant medicinal products which they handle, store or distribute.

Where and insofar as the licence relates to special medicinal products to which regulation 167 of the Regulations apply which do not have a UK authorisation and are commonly known as "specials" (refer to Guidance Note 14), the licence holder shall only import such products from an approved country for import in the case of an import into Great Britain and in the case of an import into Northern Ireland, from an EEA state in response to an order which satisfies the requirements of regulation 167 of the Regulations; and where the following conditions are complied with:

- No later than 28 days prior to each importation of a special medicinal product, the licence holder shall give written notice to the Licensing Authority stating their intention to import that special medicinal product and stating the following particulars:
  - the name of the medicinal product, being the brand name or the common name, or the scientific name, and any name, if different, under which the medicinal product is to be sold or supplied in the United Kingdom;
  - any trademark or name of the manufacturer of the medicinal product;
  - in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name or, where that constituent does not have an international non-proprietary name, a British approved name or a monograph name, the accepted scientific name or any other name descriptive of the true nature of that constituent;
  - the quantity of medicinal product which is to be imported which shall not exceed more, on any one occasion, than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment; and
  - the name and address of the manufacturer or assembler of that medicinal product in the form in which it is to be imported and, if the person who will supply that medicinal product for importation is not the manufacturer or assembler, the name and address of such supplier.
- Subject to the next bullet point below, the licence holder shall not import the special medicinal product if, before the end of 28 days from the date on which the Licensing Authority sends or gives the licence holder an acknowledgement in writing by the Licensing Authority that they have received the notice referred to in the bullet point above, the Licensing Authority have notified them in writing that the product should not be imported.
- The licence holder may import the special medicinal product referred to in the notice where they have been notified in writing by the Licensing Authority, before the end of the 28 day period referred to in the bullet point above, that the special medicinal product may be imported.
- Where the licence holder sells or supplies special medicinal products, they shall, in addition to any other records which they are required to make by the provisions of their licence, make and maintain written records relating to the batch number of the batch of the product from which the sale or supply was made and details of any adverse reaction to the product so sold or supplied of which they become aware.
- The licence holder shall import no more on any one occasion than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment, and on any such occasion shall not import more than the quantity notified to the Licensing Authority in the notification of intention to import.
- The licence holder shall inform the Licensing Authority forthwith of any matter coming to their attention which might reasonably cause the Licensing Authority to believe that the medicinal product can no longer be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

- The licence holder shall not issue any advertisement, catalogue or circular relating to the special medicinal product or make any representations in respect of that product.
- The licence holder shall cease importing or supplying a special medicinal product if they have received a notice in writing from the Licensing Authority directing that, as from a date specified in that notice, a particular product or class of products shall no longer be imported or supplied.

The licence holder shall take all reasonable precautions and exercise all due diligence to ensure that any information they provide to the Licensing Authority which is relevant to an evaluation of the safety, quality or efficacy of any medicinal product for human use which they handle, store or distribute is not false or misleading in a material particular.

Where a Wholesale Dealer's Licence relates to exempt advanced therapy medicinal products the licence holder shall keep the data for the system for the traceability of the advanced therapy medicinal products for such period, being a period of longer than 30 years, as may be specified by the Licensing Authority.

The Standard Provisions also require the holder of a Wholesale Dealer's Licence that relates to exempt advanced therapy medicinal products to obtain supplies of exempt advanced therapy medicinal products only from the holder of a Manufacturer's Licence in respect of those products or the holder of a Wholesale Dealer's Licence in respect of those products.

The licence holder must:

- distribute an exempt advanced therapy medicinal product by way of wholesale dealing only to the holder of a Wholesale Dealer's Licence in respect of those products; or a person who may lawfully administer those products, and solicited the product for an individual patient;
- establish and maintain a system ensuring that the exempt advanced therapy medicinal product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the establishment where the product is used;
- inform the Licensing Authority of any adverse reaction to any exempt advanced therapy medicinal product supplied by the holder of the Wholesale Dealer's Licence of which the holder is aware;
- keep the data referred to in paragraph 16 for a minimum of 30 years after the expiry date of the exempt advanced therapy medicinal product;
- ensure that the data referred to in paragraph 16 will, in the event that the licence is suspended, revoked or withdrawn or the licence holder becomes bankrupt or insolvent, be held available to the Licensing Authority by the holder of a Wholesale Dealer's Licence for the period described in paragraph 18 or such longer period as may be required pursuant to paragraph 44 of Schedule 4;
- not import or export any exempt advanced therapy medicinal product.

© Crown copyright 2023

Open Government Licence



Produced by the Medicines and Healthcare products Regulatory Agency.

<http://www.gov.uk/mhra>

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit

<http://www.nationalarchives.gov.uk/doc/open-government-licence> or email:

[psi@nationalarchives.gsi.gov.uk](mailto:psi@nationalarchives.gsi.gov.uk).

Where we have identified any third-party copyright material you will need to obtain permission from the copyright holders concerned.

The names, images and logos identifying the Medicines and Healthcare products Regulatory Agency are proprietary marks. All the Agency's logos are registered trademarks and cannot be used without the Agency's explicit permission.