

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations
2012 (SI 2012/1916)

Wholesale Distribution Authorisation (Human)

1. This authorisation is granted in accordance with regulation 18 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of those Regulations and the Medicines Act 1971.
2. This Wholesale Distribution Authorisation authorises distribution by way of wholesale dealing of medicinal products for human use by the authorisation holder named and storage of such products only on the premises located in the United Kingdom as specified.
3. The authorisation holder must provide and maintain such personnel, equipment and facilities as are necessary to avoid the deterioration of the medicinal products. If any change of premises is proposed prior approval must be sought from the Licensing Authority. Any proposals to make structural alterations to the premises must also be notified to the Licensing Authority.
4. The authorisation is not transferable to another legal entity.
5. The authorisation holder must not sell or supply a medicinal product, or offer it for sale or supply, unless:
 - there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in force in relation to the product
 - the sale or supply, or offer for sale or supply of the product is in accordance with the authorisation
 - the sale or supply of the medicinal is pursuant to an exemption from the requirements to hold such an authorisation (a special medicinal product), under the provisions of The Human Medicines Regulations 2012 (SI 2012/1916).
6. The authorisation holder must inform the Licensing Authority no later than 28 days prior to the sourcing from the EEA of a special medicinal product, stating the name of the medicinal product, any trademark or name of the manufacturer and their address, each active constituent, the quantity to be imported in accordance with the provision of The Human Medicines Regulations 2012 (SI 2012/1916). The authorisation holder must be able to demonstrate compliance with the European Commission 'Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products' and future updates, in accordance with, The Unlicensed Medicines Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [SI 2003/1680]
7. If the intention is to import licensed medicinal products from outside the EEA an application for a manufacturer's licence that authorises import must be made and a licence granted for that purpose before commencing with this activity. Such a licence requires the holder to have available at all times a Qualified Person who must be named on the licence.



8. If the intention is to import a special medicinal product from outside the EEA into the UK, an application for a manufacturer's "Specials" licence that authorises import must also be made and a licence granted for that purpose before commencing with this activity. Such a licence requires only that a site contact be named, no Qualified Person is required.
9. If the intention is to carry out any manufacture and/or assembly processes (e.g. packing, filling or labelling) of medicinal products, an application for a manufacturer's licence must be made and a licence granted for that purpose before commencing with this activity.
10. This Wholesale Distribution Authorisation may be suspended if any fees are not paid in full as they fall due.
11. The Medicines and Healthcare Products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).
12. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.
13. Authorisation Structure

This Wholesale Distribution Authorisation is divided into five annexes.

- (a) Annex 1: Scope of wholesale distribution authorisation
- (b) Annex 2: (Optional) Address(es) of contract wholesale distribution sites and their authorisation number
- (c) Annex 3: Name(s) of responsible person(s.)
- (d) Annex 4: (Optional) Date of Inspection on which authorisation was granted
- (e) Annex 5: Additional provisions based on national requirements

Attention is drawn to the structure of this authorisation and to its completeness in accordance with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.



14. Authorisation Holder

(a) Authorisation Holder Number: WDA(H) 15637 has been granted to –

AUTHORISATION HOLDER:	OTC DIRECT LIMITED
TRADING AS:	OTC Direct and Almus Pharmaceuticals and Cavendish Pharmaceuticals
ADDRESS:	43 COX LANE, CHESSINGTON, KT9 1SN, UNITED KINGDOM
CONTACT NAME:	[REDACTED]

- (b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing within the EEA medicinal products of the description or general classification specified, to be stored at the named premises on this authorisation.
- (c) This authorisation will continue to remain in force from the date of issue by the Licensing Authority unless cancelled, suspended, revoked or varied as to the period of its validity or relinquished by the authorisation holder.
- (d) Date granted - 20/07/2017
- (e) Authorised by -

Name: Yaseen Edo

(A person authorised to approve on behalf of the Secretary of State for Health.)

Date: 20/07/2017



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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VARIATION HISTORY

Date	Variation Detail
27/09/1996	INITIAL APPLICATION
12/09/2000	Variation to change address.
29/11/2001	Renewal with changes to update telephone and fax numbers, update site contact for site 9313 and add sites 312, 313, 314, 315, 317, 318, 320, 321 and 11299.
18/12/2001	Variation to delete site No. 3376 and update person details for [REDACTED].
04/07/2003	Variation to add Almus Pharmaceuticals as a trading style to licence.
08/12/2003	Variation to add licence holder address as a procurement site.
11/02/2004	Variation to add trading Styles.
22/03/2004	Variation to change LH name and address, also to change LH contact to [REDACTED], and to add new site to the Licence, 3376.
27/01/2006	Variation to delete [REDACTED] and add [REDACTED] change Licence address and site address.
30/07/2006	Variation to add 2 additional sites to the Licence.
28/11/2007	Variation to amend Licence Holders's address and to add Non sterile liquids to licence.
29/09/2008	Variation to add 'Special manufactured products are handled at this site' as a function to all sites plus update site contacts at all sites. Also add communication contact and address for the licence.
11/10/2008	Internal variation to amend sites 22624 and 120758 to mirror the other sites on the licence in terms of functions.
12/01/2010	Variation to all sites: remove [REDACTED] as RP and replace with [REDACTED] add [REDACTED] as Deputy RP. Sites 16313, 16314, 16315, 16326, 16333, 120758, 16307, 16308, 16306, 16304, 16311, 16312: change site name. Add an additional site: 884309.
12/01/2010	Variation to replace LHC with [REDACTED]
15/06/2010	Variation to (1) Replace [REDACTED] with [REDACTED] as RP for Sites 22624, 16304, 16306, 16307, 16308, 16311, 16312, 16313, 16314, 16315, 16326, 16333, 120758, 6963 & 884309 (2) Add Sites 17383, 93022 & 93024



25/11/2010	Variation to remove Site 17383
01/02/2011	Variation change the names of site 93022 to OTC Direct t/a North West Ostomy Supplies and site 93024 to OTC Direct t/a Cavendish Pharmaceuticals.
22/06/2012	Variation to remove Responsible Person [REDACTED] Retain Biologicals.
19/07/2012	Variation to add new procurement and handling only site 884335, remove site 22624.:
19/07/2012	Internal variation to resolve concurrency issue.
20/08/2012	Variation to amend authorisation holder to [REDACTED], to amend person authorised for communications regarding the licence to [REDACTED]
03/09/2012	Internal variation to amend site name for site 884335 to OTC Direct Limited, also add authorisation for Biologicals.
17/09/2012	Internal variation to add Cold Chain Products to site 884335
19/09/2012	Internal variation to site 884335; correct errors and add the authorisation for the handling of Unlicensed relevant medicinal products from other EEA member states.
31/01/2013	Variation to add a third party site; UDG Limited, site 5098795
07/02/2013	Internal variation to change the site name for 120758 to Almus Pharmaceuticals trading as OTCD and add the authorisation of unlicensed medicinal products to site 16304
19/07/2013	Variation to add new RP to all sites. Ammendments to sites on licence as per instructions from company.
13/10/2013	FMD update WL/WDL converted to WDA(H)
24/06/2014	Variation to remove [REDACTED] as RP and site contact for site 93024 and replace with [REDACTED] as a site contact, delete site 120758
29/10/2015	Variation to add the trading name as OTC Direct and Almus Pharmaceuticals.
29/02/2016	Variation: Amend trading style to include Almus Pharmaceuticals. Add new RP at several sites. Change site contact at NWOS. Amend NWOS address. Change licensed categories at NWOS and Cavendish. Add Site 16319 from WDA(H) 538 as this is the correct postcode.
09/06/2016	Internal variation to amend site address to UNITS 16 and 55-62, OAKHILL TRADING ESTATE, MANCHESTER, M28 3PT.
14/10/2016	Variation to add third party site Alloga UK Limited (SITE ID: 10617701) Add a new [REDACTED] to all sites.
20/03/2017	Variation to add a new third party site, Forte Pharma, SITE ID: 91641).



22/06/2017	Add three new third party sites: - Site number: 399200 - Site number: 16581122 - Site number: 16581141
10/07/2017	Internal variation
20/07/2017	Following the purchase of Forte Pharma Limited, amend the administration site of Forte (Site Number 91641) to be an OTC Direct site for when the business is integrated into OTC Direct. The existing RP for the site will remain as the RP and will transfer to the OTC Direct business. Due to the above, remove Forte (Site Number 90641) as a 3rd party site on the OTC Direct licence



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

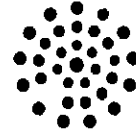
Site Name:	OTC DIRECT IVA NORTH WEST OSTOMY SUPPLIES
Address:	UNITS 16 AND 55-62, OAKHILL TRADING ESTATE, DEVONSHIRE ROAD, WORSLEY, MANCHESTER, M28 3PT, UNITED KINGDOM
MHRA Site Number:	93022

is named on Authorisation Holder number: WDA(H) 15637 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

Any restrictions or clarifying remarks related to the scope of these Wholesaling operations





Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

1.1 With a Marketing Authorisation in EEA member state(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

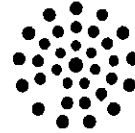
2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art 83 of 2001/83/EC

Not Authorised





MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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2012 (SI 2012/1916)

Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	OTC DIRECT TA NORTH WEST OSTOMY SUPPLIES
Address:	UNITS 16 AND 55-62, OAKHILL TRADING ESTATE, DEVONSHIRE ROAD, WORSLEY, MANCHESTER, M28 3PT, UNITED KINGDOM
MHRA Site Number:	93022

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

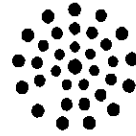
Site Name:	OTC DIRECT LIMITED
Address:	43 COX LANE, CHESSINGTON, KT9 1SN, UNITED KINGDOM
MHRA Site Number:	884335

is named on Authorisation Holder number: WDA(H) 15637 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

Any restrictions or clarifying remarks related to the scope of these Wholesaling operations





Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

- 1.1 With a Marketing Authorisation in EEA member state(s)
- 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market
- 1.3 Without a Marketing Authorisation in the EEA and not intended for EEA market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.4 Export

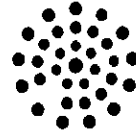
3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art 83 of 2001/83/EC

- 3.1.1 Narcotic or psychotropic products
- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products

- 3.3 Cold chain products (requiring low temperature handling)





MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations
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Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	OTC DIRECT LIMITED
Address:	43 COX LANE, CHESSINGTON, KT9 1SN, UNITED KINGDOM
MHRA Site Number:	884335

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

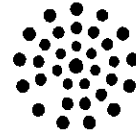
Site Name:	OTC DIRECT T/A CAVENDISH PHARMACEUTICALS
Address:	GREENFOLD WAY, WARRINGTON ROAD, ORFORD COURT, LEIGH COMMERCE PARK, LEIGH, WN7 3XJ, UNITED KINGDOM
MHRA Site Number:	93024

is named on Authorisation Holder number: WDA(H) 15637 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

Any restrictions or clarifying remarks related to the scope of these Wholesaling operations





Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

1.1 With a Marketing Authorisation in EEA member state(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

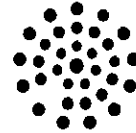
2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art 83 of 2001/83/EC

3.1.1 Narcotic or psychotropic products





MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	OTC DIRECT TV CAVENDISH PHARMACEUTICALS
Address:	GREENFOLD WAY, WARRINGTON ROAD, ORFORD COURT, LEIGH COMMERCE PARK, LEIGH, WN7 3XJ, UNITED KINGDOM
MHRA Site Number:	93024

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

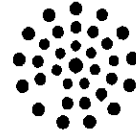
Site Name:	OTC DIRECT LIMITED
Address:	380 NEW HYTHE LANE, LARKFIELD, AYLESFORD, ME20 6RZ, UNITED KINGDOM
MHRA Site Number:	17256751

is named on Authorisation Holder number: WDA(H) 15637 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

Any restrictions or clarifying remarks related to the scope of these Wholesaling operations





Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

- 1.1 With a Marketing Authorisation in EEA member state(s)
- 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market
- 1.3 Without a Marketing Authorisation in the EEA and not intended for EEA market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.3 Supply
 - 2.5 Other Activities
- Administration only.

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art 83 of 2001/83/EC

- 3.1.1 Narcotic or psychotropic products
- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products

- 3.3 Cold chain products (requiring low temperature handling)



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	OTC DIRECT LIMITED
Address:	380 NEW HYTHE LANE, LARKFIELD, AYLESFORD, ME20 6RZ, UNITED KINGDOM
MHRA Site Number:	17256751

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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Wholesale Distribution Authorisation (Human)

Annex 2 – Address(es) of Contract Wholesale Distribution Sites and their Authorisation Number

Site Name	Address	Authorisation Holder Number	MHRA Site Number
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	2 KIRKSHAW ROAD, COATBRIDGE, ML5 5AW, UNITED KINGDOM	WDA(H) 538	16581141
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	AVENUE 1, LETCHWORTH BUSINESS PARK, LETCHWORTH, SG6 2HB, UNITED KINGDOM	WDA(H) 538	16311
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	DODD WAY, WALTON SUMMIT, BAMBER BRIDGE, PRESTON, PR5 8AE, UNITED KINGDOM	WDA(H) 538	16312
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	COFTON ROAD, MARSH BARTON TRADING ESTATE, EXETER, EX2 8QW, UNITED KINGDOM	WDA(H) 538	884309
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	UNIT 2, HIGH VIEW ROAD, SOUTH NORMANTON, ALFRETON, DE55 2DT, UNITED KINGDOM	WDA(H) 538	92677
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	UNIT 1, HIGH VIEW ROAD INDUSTRIAL ESTATE, HIGH VIEW ROAD, SOUTH NORMANTON, ALFRETON, DE55 2DT, UNITED KINGDOM	WDA(H) 538	399200
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	SWANSEA WEST INDUSTRIAL PARK, KINGSWAY, FFORESTFACH, SWANSEA, SA5 4HA, UNITED KINGDOM	WDA(H) 538	16314
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	60 VULCAN WAY, NEW ADDINGTON, CROYDON, CR9 0DB, UNITED KINGDOM	WDA(H) 538	16313
ALLOGA UK LIMITED	UNIT 1, FULWOOD 28, COMMON ROAD, HUTHWAITE, SUTTON-IN-ASHFIELD, NG17 2JN, UNITED KINGDOM	WDA(H) 15694	5098195



ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	6A GRANGE ROAD, HOUSTOUN INDUSTRIAL ESTATE, LIVINGSTON, EH54 5DE, UNITED KINGDOM	WDA(H) 538	16308
ALLOGA UK LIMITED	AMBER PARK 5 AND 6, UNIT C2, FARMWELL LANE, SOUTH NORMANTON, ALFRETON, DE55 2JX, UNITED KINGDOM	WDA(H) 15694	10617701
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	UNIT 1, AMBER PARK, BERRISTOW LANE, SOUTH NORMANTON, ALFRETON, DE55 2FH, UNITED KINGDOM	WDA(H) 538	16581122
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	CHESSINGTON SERVICE CENTRE, COX LANE, CHESSINGTON, KT9 1DH, UNITED KINGDOM	WDA(H) 538	16319
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	COX LANE, CHESSINGTON, KT9 1SN, UNITED KINGDOM	WDA(H) 538	16309
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	HINCKLEY BUSINESS PARK, DODWELLS ROAD, HINCKLEY, LE10 3BZ, UNITED KINGDOM	WDA(H) 538	16307
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	4 POOLEY CLOSE, WESTERHOPE, NEWCASTLE UPON TYNE, NE5 2TF, UNITED KINGDOM	WDA(H) 538	16326
ALLIANCE HEALTHCARE (DISTRIBUTION) LIMITED	MILLSHAW PARK AVENUE, MILLSHAW PARK TRADING ESTATE, LEEDS, LS11 0LR, UNITED KINGDOM	WDA(H) 538	16306
ALLOGA UK LIMITED	AMBER PARK 1, 2, AND 3, BERRISTOW LANE, SOUTH NORMANTON, ALFRETON, DE55 2FH, UNITED KINGDOM	WDA(H) 15694	6963



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Annex 3 – Name(s) of designated Responsible Person(s)

Personnel

Responsible Person			
Person Number	Name	Site	Role
15231391	[REDACTED]	93022	Responsible Person
619538	[REDACTED]	93022	Responsible Person
9277086	[REDACTED]	93022	Responsible Person
1464863	[REDACTED]	93022	Responsible Person
15231391	[REDACTED]	884335	Responsible Person
9277086	[REDACTED]	884335	Responsible Person
619538	[REDACTED]	884335	Responsible Person
14686928	[REDACTED]	884335	Responsible Person
14686928	M [REDACTED]	93024	Responsible Person
15231391	[REDACTED]	93024	Responsible Person
619538	[REDACTED]	93024	Responsible Person
9277086	[REDACTED]	93024	Responsible Person
123233	[REDACTED]	17256751	Responsible Person

