Medicines & Healthcare products
Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
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E14 4PU
United Kingdom

gov.uk/mhra

Mr Bharat Shah
SIGMA PHARMACEUTICALS PLC
UNIT 1 COLONIAL WAY
WATFORD
WD24 4YR
UNITED KINGDOM

WDA(H) Number: WDA(H) 8778 Version: 14

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) 8778 has been granted to –

AUTHORISATION HOLDER:	SIGMA PHARMACEUTICALS PLC

TRADING AS:	SIGMA PHARMACEUTICALS & ALMUS PHARMACEUTICALS & RX FARMA
ADDRESS:	UNIT 1 COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM
CONTACT NAME:	Mr Bharat Shah

(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 - 09/11/2018

(e) Authorised by -

Name: Asif Janjua

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

Date: 09/11/2018

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Wholesale Distribution Authorisation (Human)

VARIATION HISTORY

Date	Variation Detail
25/08/1994	INITIAL APPLICATION
23/11/1994	Renewal outstanding since 31 December 1992
30/10/1996	To add a new site O.P.D Lab Ltd at Hertfordshire.
18/11/1996	1. Add(PML) Products and and Nt code all amendments to be made to unit 6 Coloian Way.
28/01/1997	Change site name and address.
16/12/1999	Renewal with changes. 1. Amend L/H tele & fax No's. 2. Add new site. 3. Delete site (1024).
01/03/2001	Variation to add Unit 3 at Colonial Way, Watford to existing site.
11/09/2002	Variation to add trading style.
12/09/2002	Variation to change trading style
10/12/2002	Variation to add Kwikpharma as a trading style.
13/02/2003	Variation to add 3 procurement sites.
22/09/2003	Variation to change site address for Kwikpharma on licence.
28/10/2003	Variation to add Mawdsley Brooks & Co Ltd as an additional site to licence.
21/12/2004	Renewal with changes to change communication's address, to change Rp of site 11059 and to delete Wu on site 1024.
24/04/2006	1. Variation to add controlled drugs. 2. Add new site Davies International Transport Ltd 21 Brunel Way Segensworth East Fareham Hampshire PO15 5SD
03/07/2006	Internal variation to reissue licence with new company number
25/09/2006	Internal Variation to amend errors.
10/09/2007	Internal Variation to amend errors.

15/10/2007	Internal Variation.
11/09/2008	Variation to amend trading style, for site: 91641 change name to Forte Direct and replace RP with Mrs L Bassingthwaighte-Strong, for sites: 91641,91549, 89833 & 89558 update function list.
08/01/2010	Variation to add Crescent Pharma Limited as an additional storage site.
03/06/2010	Variation to add Units 5 & 7 Clive Way, Watford to site 1689019 and delete site 89833.
16/05/2011	Variation to replace Mr M F Contantine with Mr P Shirode as Responsible Person on site 21626.
30/11/2011	Variation to include additional storage sites, WD18 7QS and WD24 4PX, add additional site Movianto 5680.
06/01/2012	Internal variation to change Postcode from WD18 8AL to WD18 7QS, change all of Dr Shah's person numbers to 117336. Change 'Sterile Dressings' on other non sterile to 'Surgical dressings' and 'licensed' for sites 5680 and 3942294
11/01/2012	Internal variation to change Postcode from WD18 8AL to WD18 7QS site 3942073.
14/05/2012	Internal variation to amend site addresses for sites 1689019, 3942294 and 3942073.
21/08/2012	Variation to add three sites, Orbis Consumer Products, Auden Mckenzie, Percuro Medica Limited.
13/08/2013	Variation: to delete site 1027514, add new site 1647689
13/10/2013	FMD update WL/WDL converted to WDA(H)
20/12/2013	Internal variation to add authorisation for import for export, add 1.3, 2.4, 4.7 all Sigma sites and site 689019 also remove 2.5 and add 2.1.
22/09/2014	Variation to sites 3942294, 3942073, 1689019: add surgical dressings.
29/09/2014	Internal Variation: Update site functions
07/04/2015	Variation: 1. Add site 7142 as an additional 3rd party site.
07/05/2015	Internal variation to re-add site 10042
21/12/2015	Variation to include trading style RX Farma,
10/03/2016	Variation: 1.Add Rx Farma as a trading style. 2. PHARMACEUTICALS DIRECT LIMITED, Ambe House, Commerce Way, Edenbridge,Kent,TN8 6ED as a 3rd party site.4. Remove Aulden McKenzie,Davies,Percuro Medica and Crescent as additional sites.
16/05/2016	Variation to add '3.3 Cold chain products [requiring low temperature handling] to MHRA Site number - 3942294. Add OPD Laboratories Limited as Third Party site.
04/11/2016	Variation is to add site 89558

21/12/2016	Variation to add Mr. Hatul Shah (Person No:2811529) as an additional responsible person. Amend post code of Site No: 3942073 (Correct post code: WD18 8AL)
12/06/2017	Variation (site 1689019): - change site address to 'Units 1 & 3, Sigma House 1 & 2, HD House and A plant' - change contact details of Mr Bahrat Shah (RP)
13/03/2018	Add the following 3rd party sites: Site name: GEFCO Site number - 13659869, 16865202. Site name: Pharmaceuticals direct limited. Site number:83847. Remove 3rd party site:Forte Direct: 91641.
09/11/2018	Variation: Remove site 3942073; add sites 17190 and 2814220 as third-party sites; update trading name Addition of site - Waymade Plc [WDA(H) 6464] as contract wholesale Distribution site for two sites: Site address: Sovereign House, Miles Gray Road, Basildon, SS14 3FR, UK. (MHRA Site Number: 17190) Site address: Josselin Road, Burnt Mills Industrial Estate, Basildon, SS13 1QF, UK. (MHRA Site Number: 2814220) Removal of Forte Direct as trading name of Sigma Pharmaceuticals Plc

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Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	SIGMA PHARMACEUTICALS PLC
Address:	UNITS 1 & 3, SIGMA HOUSE 1 & 2, HD HOUSE AND A PLANT, COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM
MHRA Site Number:	1689019

is named on Authorisation Holder number: WDA(H) 8778 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

2.2 Holding

2.3 Supply

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)

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Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	SIGMA PHARMACEUTICALS PLC
Address:	UNITS 1 & 3, SIGMA HOUSE 1 & 2, HD HOUSE AND A PLANT, COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM
MHRA Site Number:	1689019

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy

4.5 Traditional Herbal Medicinal products

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Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	SIGMA PHARMACEUTICALS PLC
Address:	UNITS 4, 5, 6 & 7, CLIVE WAY, WATFORD, WD24 4PX, UNITED KINGDOM
MHRA Site Number:	3942294

is named on Authorisation Holder number: WDA(H) 8778 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

2.2 Holding

2.3 Supply

2.4 Export

2.5 Other Activities

Storage of quarantined goods and goods on hold.

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

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

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

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Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	SIGMA PHARMACEUTICALS PLC
Address:	UNITS 4, 5, 6 & 7, CLIVE WAY, WATFORD, WD24 4PX, UNITED KINGDOM
MHRA Site Number:	3942294

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy

4.5 Traditional Herbal Medicinal products

4.6 Homeopathics

4.7 Products Imported Outside of the EEA for Export to Countries Outside of the EEA

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

Site Name	Address	Authorisation Holder Number	MHRA Site Number
DAVIES INTERNATIONAL TRANSPORT LIMITED	21 BRUNEL WAY, SEGENSWORTH EAST, FAREHAM, PO15 5SD, UNITED KINGDOM	WDA(H) 62821	89558
GEFCO FORWARDING UK LIMITED	UNIT 5, MERESIDE PARK, SHIELD ROAD, ASHFORD, TW15 1BL, UNITED KINGDOM	WDA(H) 45755	16865202
OPD LABORATORIES LIMITED	UNIT 6 COLONIAL WAY, OFF RADLETT ROAD, WATFORD, WD24 4PR, UNITED KINGDOM	WDA(H) 15814	7142
GEFCO FORWARDING UK LIMITED	UNIT 1, MERESIDE PARK, SHIELD ROAD, ASHFORD, TW15 1BL, UNITED KINGDOM	WDA(H) 45755	13659869
WAYMADE PLC	JOSSELIN ROAD, BURNT MILLS INDUSTRIAL ESTATE, BASILDON, SS13 1QF, UNITED KINGDOM	WDA(H) 6464	2814220
PHARMACEUTICALS DIRECT LIMITED	A M B E HOUSE, COMMERCE WAY, EDENBRIDGE, TN8 6ED, UNITED KINGDOM	WDA(H) 18016	12454918
MOVIANTO UK LIMITED	1A PROGRESS PARK, ELSTOW, BEDFORD, MK42 9XE, UNITED KINGDOM	WDA(H) 14172	5680
WAYMADE PLC	SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM	WDA(H) 6464	17190
PHARMACEUTICALS DIRECT LIMITED	BEMIN HOUSE, CHESSINGTON INDUSTRIAL ESTATE, COX LANE, CHESSINGTON, KT9 1SG, UNITED KINGDOM	WDA(H) 18016	83847

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

Personnel

Responsible Person			
Person Number	**Name**	**Site**	**Role**
117336	Mr Bharat Shah	1689019	Responsible Person
2811529	Mr Hatul Bharat Kumar Shah	1689019	Responsible Person
117336	Mr Bharat Shah	3942294	Responsible Person
2811529	Mr Hatul Bharat Kumar Shah	3942294	Responsible Person