

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) 25298 has been granted to –

| | |
|------------------------------|--|
| AUTHORISATION HOLDER: | BROWN & BURK UK LIMITED |
| TRADING AS: | |
| ADDRESS: | 5 MARRYAT CLOSE, HOUNSLOW, TW4 5DQ, UNITED KINGDOM |
| CONTACT NAME: | Mr Jagadish Subramani |

- (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 - 13/06/2018

(e) Authorised by -

Name: Emanuela Krasteva

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

Date: 13/06/2018



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VARIATION HISTORY

| Date | Variation Detail |
|-------------|--|
| 19/10/2009 | Initial Application. |
| 09/05/2011 | Variation to add new site 2785226 for storage and handling. |
| 01/11/2011 | Variation to remove sites 38652 and 2785226. Add site 22318 |
| 03/05/2012 | Variation to add Steve Collins (person number 1106919) as an additional Responsible Person to site 86344 |
| 07/11/2012 | RBI |
| 14/11/2012 | Variation: 1. Change LHC to Dr T Olugbemiga. 2. Change site name on site id 33318 to Gantak Investments Ltd. 3. Add site activities on site id 22318. 4. Add new site id 3163392 Mawdsley-Brooks Co Ltd. 5. Add new RP's Mr S Collins and Mr B Kalola. |
| 06/06/2013 | Variation: 1. Site id 22318 change site name to Pharm pact Limited - Dartford, update Product Classes. 2. Site id 3163392 Add new RP Mr Stephen Collins and Mr Preetham Hiremat. |
| 15/10/2013 | FMD update WL/WDL converted to WDA(H) |
| 25/01/2014 | Variation to add company site UB11 1BD, Site 86344 remove Responsible Persons B Kalola and P S Hiremat, add R Wade. Delete site 22318. |
| 13/02/2015 | Variation: 1. Change LH/Communication to Jagadish Subramani. 2. Update sites 86344 & 3148289 to S/H. |
| 05/01/2017 | Variation: 1. Addition of 3 new 3rd party sites, 91444,6963,& 10617701. |
| 13/06/2018 | [1]. Add 'Export' to the activities of Brown & Burk site [86344]. [2]. Add 'Export' to the activities of Brown & Burk site [3148289]. [3]. Addition of Addition of Control drugs (Narcotic & psychotropic products) to Brown & Burk site [86344]. [4]. Addition of Addition of Control drugs (Narcotic & psychotropic products) to Brown & Burk site [3148289]. [5]. Addition of Responsible person - Alun Howells for Brown & Burk site [86344]. [6]. Addition of Responsible person - Alun Howells for Brown & Burk site [3148289]. |





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Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

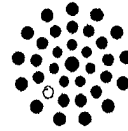
| | |
|--------------------------|--|
| Site Name: | BROWN & BURK UK LIMITED |
| Address: | 5 MARRYAT CLOSE, HOUNSLOW, TW4 5DQ, UNITED KINGDOM |
| MHRA Site Number: | 86344 |

is named on Authorisation Holder number: WDA(H) 25298 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





MHRA
Regulating Medicines and Medical Devices

WDA(H) Number: WDA(H) 25298

MHRA Site No: 86344

Version: 5

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

2.3 Supply

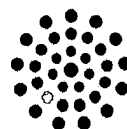
2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

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

3.1.1 Narcotic or psychotropic products





MHRA
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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: | BROWN & BURK UK LIMITED |
| Address: | 5 MARRYAT CLOSE, HOUNSLOW, TW4 5DQ, UNITED KINGDOM |
| MHRA Site Number: | 86344 |

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

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





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Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

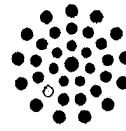
| | |
|--------------------------|---|
| Site Name: | BROWN & BURK UK LIMITED |
| Address: | REGUS BUILDING, ROOMS 105-106, 1 FURZEGROUND WAY, STOCKLEY PARK, UXBRIDGE, UB11 1BD, UNITED KINGDOM |
| MHRA Site Number: | 3148289 |

is named on Authorisation Holder number: WDA(H) 25298 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





MHRA
Regulating Medicines and Medical Devices

WDA(H) Number: WDA(H) 25298

MHRA Site No: 3148289

Version: 5

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

2.3 Supply

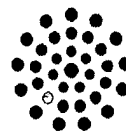
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3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

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

3.1.1 Narcotic or psychotropic products





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Annex 5 – Additional Provisions Based on National Requirements

| | |
|--------------------------|---|
| Site Name: | BROWN & BURK UK LIMITED |
| Address: | REGUS BUILDING, ROOMS 105-106, 1 FURZEGROUND WAY, STOCKLEY PARK, UXBRIDGE, UB11 1BD, UNITED KINGDOM |
| MHRA Site Number: | 3148289 |

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy



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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 |
|-----------------------------------|---|-----------------------------|------------------|
| MAWDSLEY-BROOKS & COMPANY LIMITED | QUEST 90, QUEST PARK, WHEATLEY HALL ROAD, DONCASTER, DN2 4LT, UNITED KINGDOM | WDA(H) 741 | 3163392 |
| ALLOGA UK LIMITED | AMBER PARK 1, 2, AND 3, BERRISTOW LANE, SOUTH NORMANTON, ALFRETON, DE55 2FH, UNITED KINGDOM | WDA(H) 15694 | 6963 |
| ALLOGA UK LIMITED | AMBER PARK 5 AND 6, UNIT C2, FARMWELL LANE, SOUTH NORMANTON, ALFRETON, DE55 2JX, UNITED KINGDOM | WDA(H) 15694 | 10617701 |
| MAWDSLEY BROOKS & COMPANY LIMITED | PARKWAY DRIVE, UNIT 7, PARKWAY ONE BUSINESS CENTRE, SHEFFIELD, S9 4WU, UNITED KINGDOM | WDA(H) 741 | 91444 |

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

Personnel

| <u>Responsible Person</u> | | | |
|----------------------------------|---------------------------|--------------------|--------------------|
| <u>Person Number</u> | <u>Name</u> | <u>Site</u> | <u>Role</u> |
| 19239906 | Dr Alun Howells | 86344 | Responsible Person |
| 1106919 | Mr Stephen Albert Collins | 86344 | Responsible Person |
| 50341 | Mr R C Wade | 86344 | Responsible Person |
| 50341 | Mr R C Wade | 3148289 | Responsible Person |
| 19239906 | Dr Alun Howells | 3148289 | Responsible Person |