

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Medicines Act 1968 as amended

Wholesale Dealer's Licence

SECTION 1

1. This licence is granted in accordance with section 8 (3) and (3A) of The Medicines Act 1968 as amended and is subject to the provisions of The Medicines Act 1968 as amended and 1971 and The Medicines For Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789). By virtue of section 47 of the Act, when new standard provisions are made by regulation such provisions shall be deemed to be incorporated in existing licences as from the end of the three months from the date on which the regulations come into operation but it is provided that at any time before the end of that period the holder may apply to the Licensing Authority to direct that the new provisions should not be incorporated or will apply subject to any exception or modification specified in the application.
2. It authorises distribution by way of wholesale dealing within the EEA of medicinal products by the licence holder named and storage of such products only on the premises specified.
3. The licence 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. If the business should change hands, the company or person taking over the business will need to obtain their own licence, if they do not already have one, before commencing wholesale dealing in medicinal products.

Attention is drawn to the structure of this licence (as detailed on page 2 of Section 1) and to its completeness in accordance with that structure. This is of particular relevance where the holder of the licence is using it as evidence to a third party in support of claims to carry out those operations and activities to which this licence applies on premises and using personnel covered by this licence.



SECTION 1 (continued)

4. A medicinal product may be placed on the market in the United Kingdom only in accordance with a marketing authorisation or pursuant to an exemption from the requirements to hold a marketing authorisation granted under the provisions of the Medicines for Human Use (Marketing Authorisations) Regulations 1994 as amended (SI 1994/3144) or by relevant European Community provisions ("an exempt medicinal product"). Wholesale dealers may only distribute such products.
5. The Licence holder must inform the Licensing Authority no later than 28 days prior to the sourcing from the EEA of an exempt 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 Medicines For Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789). The Licence 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].
6. If a licence holder intends 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. Such a licence requires the holder to have available at all times a Qualified Person who must be named on the licence.
7. If a licence holder intends to import exempt medicinal products from outside the EEA into the UK, an application for a manufacturer's licence that authorises import must also be made and a licence granted for that purpose.
8. If a licence holder intends to carry out any manufacture and/or assembly process (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.
9. A licence may be suspended if any fees are not paid in full as they fall due.
10. The Medicines and Healthcare products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Medicines Act 1968 as amended.
11. Further information and specified guidelines may be obtained from the MHRA website (www.mhra.gov.uk).
12. Licence Structure

This Licence is divided into three sections.

- (a) Section 1 (this section) identifies the licence holder and holds the authorising name for the issue of the licence. This section would not usually be replaced during routine variations of the licence unless the licence holder details are varied.
- (b) Section 2 lists variations to the licence. A replacement section 2 will be issued each time the licence is varied.
- (c) Section 3 contains the details relating to each site named on the licence. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.
- (d) The licence holder is required to attach to his licence any replacement pages issued by the Licensing Authority and to mark or destroy superseded pages as to render them invalid.





13. Licence Holder

(a) WL Number: WL 4321 has been granted to –

| | |
|-----------------|------------|
| LICENCE HOLDER: | DURBIN PLC |
|-----------------|------------|

| | |
|---------------|---|
| TRADING AS: | |
| ADDRESS: | 180 NORTHOLT ROAD, SOUTH HARROW, MIDDLESEX, HA2 0LT, UNITED KINGDOM |
| CONTACT NAME: | MR P O'REILLY |

- (b) This licence permits the licence 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 and using the named personnel in accordance with Section 3 of this licence.
- (c) This licence will continue to remain in force from the date of issue by the Licensing Authority unless suspended, revoked or varied as to the period of its validity or relinquished by the licence holder.
- (d) Date granted - 01/09/2009
- (e) Authorised by -

Name: Sean Kaiser

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

Date: 01/09/2009



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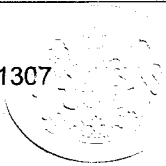
SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

| Date | Variation Detail |
|------------|---|
| 01/01/1993 | INITIAL APPLICATION |
| 11/04/1996 | Renewal application no changes made. |
| 24/11/2000 | Variation to change L/H name, tel/fax nos. and postcode. |
| 06/07/2001 | Renewal with no changes except update of telephone and fax numbers |
| 01/08/2002 | Variation to add an additional site to licence. |
| 18/05/2004 | Variation to add and delete storage and distribution site |
| 02/02/2005 | Variation - Amend Address and change RP to Mr P L O'Reilly. |
| 02/03/2007 | Variation to add Linda Guinnessy as additional RP. |
| 21/03/2007 | Internal Variation to add Linda Guinnessy as additional RP on both sites and re-add RP Mr P O'Reilly to site 92333 as he shouldn't have been removed. |
| 22/11/2007 | Internal Variation |
| 01/09/2009 | Variation to (1) Add new site: 12 Fairway Drive, Greenford, Middlesex, UB6 8PW (2) Add Miss Dipti Amin as an additional RP to all sites |





MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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SECTION 3 - SITE INFORMATION

The premises –

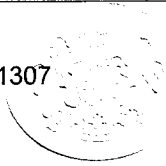
| | |
|--------------------------|--|
| Site Name: | DURBIN PLC |
| Address: | 180 NORTHOLT ROAD, SOUTH HARROW, MIDDLESEX, HA2 0LT, UNITED KINGDOM |
| MHRA Site Number: | 31307 |

is named on WL number: WL 4321 and licensed 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:





SECTION 3 - SITE INFORMATION (continued)

USE OF PRODUCTS AT SITE

| USE OF PRODUCTS AT SITE | |
|---|-----|
| <i>Administration to human beings</i> | Yes |
| SITE TYPES | |
| <i>Distribution only</i> | Yes |
| <i>Storage and Handling (picking of goods)</i> | Yes |
| <i>Procurement/administration only (no storage)</i> | No |

| CATEGORIES OF PRODUCTS HANDLED AT THIS SITE | |
|--|-----|
| <i>Prescription Only Medicines</i> | Yes |
| <i>General Sales List</i> | Yes |
| <i>Pharmacy</i> | Yes |
| <i>Traditional Herbal Medicinal Products</i> | Yes |
| <i>Biological Products</i> | Yes |





SECTION 3 - SITE INFORMATION (continued)

| PRODUCT CLASSES | |
|--|----------|
| <i>Large volume sterile liquids</i> | Licensed |
| <i>Small volume sterile liquids (including eye drops)</i> | Licensed |
| <i>Semi-solid sterile dosage forms (including sterile creams and ointments)</i> | Licensed |
| <i>Solid sterile dosage forms (including sterile powders)</i> | Licensed |
| <i>Other sterile products (as specified) Dressings and Equipment</i> | Licensed |
| <i>Non-sterile liquids (including solutions, syrups and suspensions)</i> | Licensed |
| <i>Semi-solid non-sterile dosage forms (including non-sterile creams and ointments)</i> | Licensed |
| <i>Solid non-sterile dosage forms (including tablets, capsules, suppositories and powders)</i> | Licensed |
| <i>Other non-sterile products (as specified) – Equipment</i> | Licensed |
| <i>Medical gases</i> | Licensed |

| SPECIFIC SITE ACTIVITIES | |
|---|----------|
| <i>Unlicensed medicinal products from within the EEA handled at this site</i> | Licensed |
| <i>“Special” manufactured products handled at this site</i> | Licensed |
| <i>Parallel imported medicinal products handled at this site</i> | Licensed |





SECTION 3 - SITE INFORMATION (continued)

Personnel

| <u>Person Number</u> | <u>Responsible Person</u> |
|-----------------------------|----------------------------------|
| | <u>Name</u> |
| 122479 | Mr P O'Reilly |
| 1122921 | Mrs L Guinnessy |
| 146208 | Ms D Amin |

Key to Role:

RP –Responsible Person





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SECTION 3 - SITE INFORMATION

The premises –

| | |
|--------------------------|---|
| Site Name: | DURBIN PLC |
| Address: | 19 FAIRWAY DRIVE, GREENFORD, MIDDLESEX, UB6 8PW, UNITED KINGDOM |
| MHRA Site Number: | 92333 |

is named on WL number: WL 4321 and licensed to perform the following:

4. Those operations as specified.
5. Those descriptions of products or classes of product as specified
6. The personnel named to carry out the roles as specified.

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





SECTION 3 - SITE INFORMATION (continued)

USE OF PRODUCTS AT SITE

| USE OF PRODUCTS AT SITE | |
|---|-----|
| <i>Administration to human beings</i> | Yes |
| SITE TYPES | |
| <i>Distribution only</i> | Yes |
| <i>Storage and Handling (picking of goods)</i> | Yes |
| <i>Procurement/administration only (no storage)</i> | No |

| CATEGORIES OF PRODUCTS HANDLED AT THIS SITE | |
|--|-----|
| <i>Prescription Only Medicines</i> | Yes |
| <i>General Sales List</i> | Yes |
| <i>Pharmacy</i> | Yes |
| <i>Traditional Herbal Medicinal Products</i> | Yes |
| <i>Biological Products</i> | Yes |





SECTION 3 - SITE INFORMATION (continued)

| PRODUCT CLASSES | |
|--|----------|
| <i>Large volume sterile liquids</i> | Licensed |
| <i>Small volume sterile liquids (including eye drops)</i> | Licensed |
| <i>Semi-solid sterile dosage forms (including sterile creams and ointments)</i> | Licensed |
| <i>Solid sterile dosage forms (including sterile powders)</i> | Licensed |
| <i>Other sterile products (as specified)</i> <i>Dressings and Equipment</i> | Licensed |
| <i>Non-sterile liquids (including solutions, syrups and suspensions)</i> | Licensed |
| <i>Semi-solid non-sterile dosage forms (including non-sterile creams and ointments)</i> | Licensed |
| <i>Solid non-sterile dosage forms (including tablets, capsules, suppositories and powders)</i> | Licensed |
| <i>Other non-sterile products (as specified) – Equipment</i> | Licensed |
| <i>Medical gases</i> | Licensed |

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| <i>Unlicensed medicinal products from within the EEA handled at this site</i> | Licensed |
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SECTION 3 - SITE INFORMATION (continued)

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|-----------------------------|----------------------------------|
| | <u>Name</u> |
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| 122479 | Mr P O'Reilly |
| 146208 | Ms D Amin |

Key to Role:

RP –Responsible Person



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SECTION 3 - SITE INFORMATION

The premises –

| | |
|--------------------------|--|
| Site Name: | DURBIN PLC |
| Address: | 12 FAIRWAY DRIVE, GREENFORD, UB6 8PW, UNITED KINGDOM |
| MHRA Site Number: | 936068 |

is named on WL number: WL 4321 and licensed to perform the following:

- 7. Those operations as specified.
- 8. Those descriptions of products or classes of product as specified
- 9. The personnel named to carry out the roles as specified.

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





SECTION 3 - SITE INFORMATION (continued)

USE OF PRODUCTS AT SITE

| USE OF PRODUCTS AT SITE | |
|---|-----|
| <i>Administration to human beings</i> | Yes |
| SITE TYPES | |
| <i>Distribution only</i> | No |
| <i>Storage and Handling (picking of goods)</i> | Yes |
| <i>Procurement/administration only (no storage)</i> | No |

| CATEGORIES OF PRODUCTS HANDLED AT THIS SITE | |
|--|-----|
| <i>Prescription Only Medicines</i> | Yes |
| <i>General Sales List</i> | Yes |
| <i>Pharmacy</i> | Yes |
| <i>Traditional Herbal Medicinal Products</i> | Yes |
| <i>Biological Products</i> | Yes |





SECTION 3 - SITE INFORMATION (continued)

| PRODUCT CLASSES | |
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| <i>Non-sterile liquids (including solutions, syrups and suspensions)</i> | Licensed |
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