Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Ms Linsey White
ROYLANCE STABILITY STORAGE LIMITED
BIOCITY SCOTLAND
BO'NESS ROAD
MOTHERWELL
ML1 5UH
UNITED KINGDOM

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

1. This authorisation is granted in accordance with The Human Medicines Regulations 2012 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 an authorisation (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
    - 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
    - the sale or supply of the medicinal product is pursuant to regulation 174 (supply in response to spread of pathogenic agents etc) under the provisions of The Human Medicines Regulations 2012

6. If authorised the authorisation holder must inform the Licensing Authority no later than 28 days prior to the import of a special medicinal from a listed approved country for import, 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. The authorisation holder must be able to demonstrate compliance 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 not from an approved country for import list 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 not from an approved country for import 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.

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: Names(s) of the Responsible Person for import
    (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) 51381 has been granted to –

AUTHORISATION HOLDER:	ROYLANCE STABILITY STORAGE LIMITED

TRADING AS:	
ADDRESS:	BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM
CONTACT NAME:	Ms Linsey White

(b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing 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 - 18/03/2025

(e) Authorised by -

Name: Zdravka Ivanova

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

Date: 18/03/2025

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

VARIATION HISTORY

Date	Variation Detail
18/03/2025	Initial application ROYLANCE STABILITY STORAGE LIMITED WDA(H) 51381

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 4 – Name(s) of designated Responsible Person(s) for Import

Personnel

NAME:	ADDRESS:
Mr Gary Wilcock	BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM

Has/Have been designated the Responsible Person(s) for Import for WDA(H) 51381

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 MHRA Site No: 37418053 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	ROYLANCE STABILITY STORAGE LIMITED (WISHAW)
Address:	UNIT 1 EXCELSIOR PARK, NETHERTON INDUSTRIAL ESTATE, WISHAW, ML2 0EG, UNITED KINGDOM
MHRA Site Number:	37418053

is named on Authorisation Holder number: WDA(H) 51381 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

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WDA(H) Number: WDA(H) 51381 MHRA Site No: 37418053 Version: 1

Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

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)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

2.3 Supply

2.6 Products imported from countries on a list

2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.3 Immunological medicinal products

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 MHRA Site No: 37418053 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	ROYLANCE STABILITY STORAGE LIMITED (WISHAW)
Address:	UNIT 1 EXCELSIOR PARK, NETHERTON INDUSTRIAL ESTATE, WISHAW, ML2 0EG, UNITED KINGDOM
MHRA Site Number:	37418053

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 MHRA Site No: 18816730 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	ROYLANCE STABILITY STORAGE LIMITED
Address:	BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM
MHRA Site Number:	18816730

is named on Authorisation Holder number: WDA(H) 51381 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 "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.3 Supply

2.6 Products imported from countries on a list

2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 MHRA Site No: 18816730 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	ROYLANCE STABILITY STORAGE LIMITED
Address:	BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM
MHRA Site Number:	18816730

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 MHRA Site No: 37418051 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	ROYLANCE STABILITY STORAGE LIMITED
Address:	ELPHINSTONE SQUARE, DEANS INDUSTRIAL ESTATE, LIVINGSTONE, EH54 8RG, UNITED KINGDOM
MHRA Site Number:	37418051

is named on Authorisation Holder number: WDA(H) 51381 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

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Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

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)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

2.3 Supply

2.6 Products imported from countries on a list

2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 MHRA Site No: 37418051 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	ROYLANCE STABILITY STORAGE LIMITED
Address:	ELPHINSTONE SQUARE, DEANS INDUSTRIAL ESTATE, LIVINGSTONE, EH54 8RG, UNITED KINGDOM
MHRA Site Number:	37418051

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

4.1 Prescription Only Medicines

4.2 General Sales List

4.4 Pharmacy

Medicines & Healthcare products Regulatory Agency

MHRA

WDA(H) Number: WDA(H) 51381 Version: 1

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

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

Personnel

Responsible Person			
Person Number	**Name**	**Site**	**Role**
1476496	Mr Gary Wilcock	37418053	Responsible Person
1476496	Mr Gary Wilcock	18816730	Responsible Person
1476496	Mr Gary Wilcock	37418051	Responsible Person