

# Medicines and Healthcare products Regulatory Agency

## WHOLESALE DISTRIBUTION AUTHORISATION

### (MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 31644

2. Name of Authorisation Holder CLINIGEN HEALTHCARE LIMITED

3. Legally registered address of Authorisation Holder CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM

CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM

4. Address(es) of Site(s) CLINIGEN HEALTHCARE LIMITED, UNIT 3, CANADA ROAD, BYFLEET, WEST BYFLEET, KT14 7JL, UNITED KINGDOM

CLINIGEN HEALTHCARE LIMITED, IDIS HOUSE, CHURCHFIELD ROAD, WEYBRIDGE, KT13 8DB, UNITED KINGDOM

5. Scope of authorisation (complete for each site under 4) ANNEX 1

6. Legal basis of authorisation Regulation 18 of the Human Medicines Regulations 2012

7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation Confidential

8. Date 17/02/2025

9. Annexes attached Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 Additional provisions

#### ANNEX 1

#### SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

**CLINIGEN HEALTHCARE LIMITED**, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM

##### 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)

1.2 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

1.3 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

## **2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.1 Procurement

2.4 Export

2.6 Products imported from countries on a list

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

2.6b Products not certified under Article 51 of Directive 2001/83/EC

## **3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

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)

### **Any restrictions or clarifying remarks (for all users)**

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List, 4.4 Pharmacy

Name and address of the site:

**CLINIGEN HEALTHCARE LIMITED**, UNIT 3, CANADA ROAD, BYFLEET, WEST BYFLEET, KT14 7JL, UNITED KINGDOM

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1.3 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

## **2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.2 Holding

2.3 Supply

2.4 Export

2.6 Products imported from countries on a list

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

2.6b Products not certified under Article 51 of Directive 2001/83/EC

### 3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

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)

#### Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List, 4.4 Pharmacy

Name and address of the site:

**CLINIGEN HEALTHCARE LIMITED**, IDIS HOUSE, CHURCHFIELD ROAD, WEYBRIDGE, KT13 8DB, UNITED KINGDOM

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2.1 Procurement

2.4 Export

2.6 Products imported from countries on a list

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

2.6b Products not certified under Article 51 of Directive 2001/83/EC

### 3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.1.4 Radiopharmaceutical (including radionuclide kits)

3.3 Cold chain products (requiring low temperature handling)

#### Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List, 4.4 Pharmacy