

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 8778
2. Name of Authorisation Holder	SIGMA PHARMACEUTICALS PLC
3. Legally registered address of Authorisation Holder	SIGMA PHARMACEUTICALS PLC, FIFTH FLOOR, WATSON HOUSE, 54-60 BAKER STREET, LONDON, W1U 7BU, UNITED KINGDOM SIGMA PHARMACEUTICALS PLC, UNIT 4 IMPERIAL PARK, IMPERIAL WAY, WATFORD, WD24 4PP, UNITED KINGDOM SIGMA PHARMACEUTICALS PLC, UNIT 3 IMPERIAL PARK, IMPERIAL WAY, WATFORD, WD24 4PP, UNITED KINGDOM
4. Address(es) of Site(s)	SIGMA PHARMACEUTICALS PLC, UNITS 1 & 3, SIGMA HOUSE 1 & 2, HD HOUSE AND A PLANT, COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM SIGMA PHARMACEUTICALS PLC, UNIT 2, MOLESEY BUSINESS CENTRE, CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, 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	27/06/2024
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:

SIGMA PHARMACEUTICALS PLC, UNIT 4 IMPERIAL PARK, IMPERIAL WAY, WATFORD, WD24 4PP, 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

1.4 With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

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

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

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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

SIGMA PHARMACEUTICALS PLC, UNIT 3 IMPERIAL PARK, IMPERIAL WAY, WATFORD, WD24 4PP, 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)

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2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

2.3 Supply

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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

SIGMA PHARMACEUTICALS PLC, UNITS 1 & 3, SIGMA HOUSE 1 & 2, HD HOUSE AND A PLANT, COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM

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Name and address of the site:

SIGMA PHARMACEUTICALS PLC, UNIT 2, MOLESEY BUSINESS CENTRE, CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, 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)

1.3 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

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