Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 43720
2. Name of Authorisation Holder	SPHERE PHARMA SOLUTIONS LIMITED
3. Legally registered address of Authorisation Holder	SPHERE PHARMA SOLUTIONS LIMITED, UNIT 28, CROMWELL INDUSTRIAL ESTATE, STAFFA ROAD, LONDON, E10 7QZ, UNITED KINGDOM
4. Address(es) of Site(s)	SPHERE PHARMA SOLUTIONS LIMITED, UNIT 28, CROMWELL INDUSTRIAL ESTATE, STAFFA ROAD, LONDON, E10 7QZ, 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	21/10/2022
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:

SPHERE PHARMA SOLUTIONS LIMITED, UNIT 28, CROMWELL INDUSTRIAL ESTATE, STAFFA ROAD, LONDON, E10 7QZ, 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) 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) and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

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2.1 Procurement
2.2 Holding
2.3 Supply
2.4 Export
2.5 Other Activities Clinical trials supplies (comparator products from third countries)Medicinal products supplied for use as bioequivalence studies within EU and third countriesSupply specials as and when requiredAll products will be non cold chain
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

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

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