Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 34367
2. Name of Authorisation Holder	SWEDISH ORPHAN BIOVITRUM LIMITED
3. Legally registered address of Authorisation Holder	SWEDISH ORPHAN BIOVITRUM LIMITED, SUITE 2, BUILDING 3, RIVERSIDE SUITE, GRANTA PARK, GREAT ABINGTON, CAMBRIDGE, CB21 6AD, UNITED KINGDOM
4. Address(es) of Site(s)	SWEDISH ORPHAN BIOVITRUM LIMITED, SUITE 2, BUILDING 3, RIVERSIDE SUITE, GRANTA PARK, GREAT ABINGTON, CAMBRIDGE, CB21 6AD, 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	29/08/2024
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:

SWEDISH ORPHAN BIOVITRUM LIMITED, SUITE 2, BUILDING 3, RIVERSIDE SUITE, GRANTA PARK, GREAT ABINGTON, CAMBRIDGE, CB21 6AD, 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

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

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

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

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