Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 25043

ASTELLAS PHARMA EUROPE LIMITED 2. Name of Authorisation Holder

3. Legally registered address of ASTELLAS PHARMA EUROPE LIMITED, 300 DASHWOOD LANG ROAD, BOURNE

Authorisation Holder BUSINESS PARK, ADDLESTONE, KT15 2NX, UNITED KINGDOM

ASTELLAS PHARMA EUROPE LIMITED, 300 DASHWOOD LANG ROAD, BOURNE

BUSINESS PARK, ADDLESTONE, KT15 2NX, UNITED KINGDOM

4. Address(es) of Site(s) ASTELLAS PHARMA EUROPE LIMITED, 200 DASHWOOD LANG ROAD, BOURNE

BUSINESS PARK, ADDLESTONE, KT15 2NX, UNITED KINGDOM

5. Scope of authorisation (complete for

each site under 4)

ANNEX 1

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

7. Name of responsible officer of the competent authority of the member

state granting the wholesaling

authorisation

Confidential

27/09/2022 8. Date

> Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional)

9. Annexes attached 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:

ASTELLAS PHARMA EUROPE LIMITED, 300 DASHWOOD LANG ROAD, BOURNE BUSINESS PARK, ADDLESTONE, KT15 2NX, **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

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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

- 2.1 Procurement
- 2.3 Supply
- 2.4 Export

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 Name and address of the site:

ASTELLAS PHARMA EUROPE LIMITED, 200 DASHWOOD LANG ROAD, BOURNE BUSINESS PARK, ADDLESTONE, KT15 2NX 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
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