

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 25043
2. Name of Authorisation Holder ASTELLAS PHARMA EUROPE LIMITED
3. Legally registered address of Authorisation Holder 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, 300 DASHWOOD LANG ROAD, BOURNE BUSINESS PARK, ADDLESTONE, KT15 2NX, UNITED KINGDOM
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
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 27/09/2022
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:

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

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

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