# Medicines and Healthcare products Regulatory Agency

## WHOLESALE DISTRIBUTION AUTHORISATION

## (MEDICINAL PRODUCTS FOR HUMAN USE)

| | |
|---|---|
| 1. Authorisation Number | UK WDA(H) 166 |
| 2. Name of Authorisation Holder | ASTELLAS PHARMA LIMITED |
| 3. Legally registered address of Authorisation Holder | ASTELLAS PHARMA LIMITED, 300 DASHWOOD LANG ROAD, BOURNE BUSINESS PARK, ADDLESTONE, KT15 2NX, UNITED KINGDOM |
| 4. Address(es) of Site(s) | ASTELLAS PHARMA LIMITED, 300 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 | 18/03/2026 |
| 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 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) and intended for the UK market

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.1 Procurement

MHRA-GMDP MHRA-GMDP MHRA

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**

3.3 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

MHRA-GMDP MHRA MHRA-GMDP MHRA