

# Medicines and Healthcare products Regulatory Agency

## WHOLESALE DISTRIBUTION AUTHORISATION

### (MEDICINAL PRODUCTS FOR HUMAN USE)

|  |   |
|--|---|
| 1. Authorisation Number  | UK WDA(H) 57072   |
| 2. Name of Authorisation Holder  | KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED  |
| 3. Legally registered address of Authorisation Holder  | KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED, 3 GALABANK BUSINESS PARK, QUEEN STREET, GALASHIELS, TD1 1QH, UNITED KINGDOM   |
| 4. Address(es) of Site(s)  | KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED, 3 GALABANK BUSINESS PARK, QUEEN STREET, GALASHIELS, TD1 1QH, 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  | 07/03/2025  |
| 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:

**KYOWA KIRIN INTERNATIONAL UK NEWCO LIMITED**, 3 GALABANK BUSINESS PARK, QUEEN STREET, GALASHIELS, TD1 1QH, 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)

1.3 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

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**

3.1.1 Narcotic or psychotropic products

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, 4.4 Pharmacy