

# Medicines and Healthcare products Regulatory Agency

## WHOLESALE DISTRIBUTION AUTHORISATION

### (MEDICINAL PRODUCTS FOR HUMAN USE)

|  |   |
|--|---|
| 1. Authorisation Number  | UK WDA(H) 31  |
| 2. Name of Authorisation Holder  | ROCHE PRODUCTS LIMITED  |
| 3. Legally registered address of Authorisation Holder  | ROCHE PRODUCTS LIMITED, 6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, UNITED KINGDOM   |
| 4. Address(es) of Site(s)  | ROCHE PRODUCTS LIMITED, 6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, 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  | 03/10/2022  |
| 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:

**ROCHE PRODUCTS LIMITED**, 6 FALCON WAY, SHIRE PARK, WELWYN GARDEN CITY, AL7 1TW, 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

2.4 Export

### 3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

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