Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 56256
2. Name of Authorisation Holder	ORAAPHARMA LTD
3. Legally registered address of Authorisation Holder	ORAAPHARMA LTD, UNIT H, ABBEYGATE BUSINESS CENTRE, HITCHIN ROAD, LUTON, LU2 0ER, UNITED KINGDOM
4. Address(es) of Site(s)	ORAAPHARMA LTD, UNIT H, ABBEYGATE BUSINESS CENTRE, HITCHIN ROAD, LUTON, LU2 0ER, 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	03/01/2025
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:

ORAAPHARMA LTD, UNIT H, ABBEYGATE BUSINESS CENTRE, HITCHIN ROAD, LUTON, LU2 0ER, 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) and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

MHRA-GMDP MHRA-GMDP MHRA

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

3.3 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, 4.2 General Sales List, 4.4 Pharmacy, 4.5 Traditional Herbal Medicinal products

MHRA-GMDP MHRA MHRA-GMDP MHRA