Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 48028

2. Name of Authorisation Holder OPTIMAL PHARMA LTD

3. Legally registered address of

Authorisation Holder

4. Address(es) of Site(s)

OPTIMAL PHARMA LTD, UNIT D1, IVINGHOE BUSINESS CENTRE, BLACKBURN ROAD, TOWNSEND INDUSTRIAL ESTATE, HOUGHTON REGIS, DUNSTABLE, LU5 5BQ, UNITED

KINGDOM

OPTIMAL PHARMA LIMITED, UNIT D1, IVINGHOE BUSINESS CENTRE, BLACKBURN

ROAD, TOWNSEND INDUSTRIAL ESTATE, HOUGHTON REGIS, DUNSTABLE, LU5 5BQ,

UNITED KINGDOM

5. Scope of authorisation (complete for

each site under 4)

9. Annexes attached

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 Confidential

granting the wholesaling authorisation

8. Date 16/04/2025

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:

OPTIMAL PHARMA LIMITED, UNIT D1, IVINGHOE BUSINESS CENTRE, BLACKBURN ROAD, TOWNSEND INDUSTRIAL ESTATE, HOUGHTON REGIS, DUNSTABLE, LU5 5BQ, 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)
- 1.4 With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

Issue Date: 16 Apr 2025

- 2.2 Holding
- 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

- 3.1.2 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

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