Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 17509

2. Name of Authorisation Holder ESTEVE PHARMACEUTICALS LTD

3. Legally registered address of

Authorisation Holder

ESTEVE PHARMACEUTICALS LTD, THE ROUNDHOUSE, THE COURTYARD BARNS,

CHOKE LANE, COOKHAM DEAN, MAIDENHEAD, SL6 6PT, UNITED KINGDOM

4. Address(es) of Site(s)

ESTEVE PHARMACEUTICALS LTD, THE ROUNDHOUSE, THE COURTYARD BARNS,

CHOKE LANE, COOKHAM DEAN, MAIDENHEAD, SL6 6PT, 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 granting the wholesaling authorisation

Confidential

8. Date 27/01/2025

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:

ESTEVE PHARMACEUTICALS LTD, THE ROUNDHOUSE, THE COURTYARD BARNS, CHOKE LANE, COOKHAM DEAN, MAIDENHEAD, SL6 6PT, 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
- 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

Issue Date: 27 Jan 2025

- 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, 4.2 General Sales List, 4.4 Pharmacy

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