

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 33967
2. Name of Authorisation Holder EISAI EUROPE LIMITED
3. Legally registered address of Authorisation Holder EISAI EUROPE LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM
4. Address(es) of Site(s) EISAI EUROPE LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM
EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, 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 31/05/2024
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:

EISAI EUROPE LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, 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

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines

Name and address of the site:

EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, 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

2.2 Holding

2.3 Supply

2.4 Export

2.5 Other Activities

Procurement / administration. Manufacturing of products, prior to distribution, under MIA 32301 (site 726219)

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines