

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

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| 1. Registration Number | UK API 22352 |
| 2. Name or corporate name of registrant | VERTEX PHARMACEUTICALS (EUROPE) LIMITED |
| 3. Permanent or legal address of registrant | VERTEX PHARMACEUTICALS (EUROPE) LIMITED, 86-88 JUBILEE AVENUE, MILTON PARK, MILTON, ABINGDON, OX14 4RW, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | VERTEX PHARMACEUTICALS (EUROPE) LIMITED, C/O VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, UNITED KINGDOM |
| 5. National legal basis of registration | Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916) |
| 6. Name of responsible officer of the competent authority of the member state validating the registration | Confidential |
| 7. Date | 02/10/2025 |

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

VERTEX PHARMACEUTICALS (EUROPE) LIMITED, C/O VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

IVACAFTOR
(3000016532)

3rd Country Manufacturer

SHANGHAI SYNTHALL PHARMACEUTICAL CO., LIMITED, NO. 9 YUEGONG ROAD, JINSHAN DISTRICT, SHANGHAI, CN-201507, CHINA

3rd Country Distributor

DEUTIVACAFTOR (3000020159) **CHANGZHOU SYNTHALL PHARMACEUTICAL CO., LIMITED**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA

SUZETRIGINE (3000024370) **CHANGZHOU SYNTHALL PHARMACEUTICAL CO., LIMITED**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA

ELEXACAFTOR (1000020769) **CHANGZHOU SYNTHALL PHARMACEUTICAL CO., LIMITED**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA

TEZACAFTOR (1000019934) **CHANGZHOU SYNTHALL PHARMACEUTICAL CO., LIMITED**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA

SHANGHAI STA PHARMACEUTICAL PRODUCT CO., LIMITED, BUILDING 15, 31 YIWEI ROAD, WAIGAOQIAO FREE TRADE ZONE, SHANGHAI, CN-200131, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

IVACAFTOR (3000016532)

DEUTIVACAFTOR (3000020159)

SUZETRIGINE (3000024370)

ELEXACAFTOR (1000020769)

LUMACAFTOR (1000017498)

VANZACAFTOR (3000023001)

TEZACAFTOR (1000019934)