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

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, C/O VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, 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	05/06/2026

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	3rd Country Manufacturer	3rd Country Distributor
ELEXACAFTOR (1000020769)	**CHANGZHOU SYNTHEALL PHARMACEUTICAL CO., LIMITED**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA	

MHRA-GMDP MHRA-GMDP MHRA

TEZACAFTOR (1000019934)	**CHANGZHOU SYNTHEALL 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
DEUTIVACAFTOR (3000020159)	**CHANGZHOU SYNTHEALL PHARMACEUTICAL CO., LIMITED**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA
IVACAFTOR (3000016532)	**SHANGHAI SYNTHEALL PHARMACEUTICAL CO., LIMITED**, NO. 9 YUEGONG ROAD, JINSHAN DISTRICT, SHANGHAI, CN-201507, CHINA
SUZETRIGINE (3000024370)	**LAURUS LABS LIMITED**, PLOT NO. 25, 25A-25K, APSEZ DE NOTIFIED AREA, LALAMKODURU VILLAGE, RAMBILLI MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531011, INDIA **CHANGZHOU SYNTHEALL PHARMACEUTICAL CO., LIMITED**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

VANZACAFTOR (3000023001)

ELEXACAFTOR (1000020769)

TEZACAFTOR (1000019934)

LUMACAFTOR (1000017498)

DEUTIVACAFTOR (3000020159)

IVACAFTOR (3000016532)

SUZETRIGINE (3000024370)

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