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

UK API 25

1. Registration Number 2. Name or corporate name of registrant ORGANON PHARMA (UK) LIMITED ORGANON PHARMA (UK) LIMITED, SHOTTON LANE, 3. Permanent or legal address of registrant CRAMLINGTON, NE23 3JU, UNITED KINGDOM ORGANON PHARMA (UK) LIMITED, SHOTTON LANE, 4. Address(es) of site(s) where registered activities take place CRAMLINGTON, NE23 3JU, UNITED KINGDOM Regulation 327 of The Human Medicines Regulations 2012 (SI

5. National legal basis of registration

2012/1916)

Confidential

6. Name of responsible officer of the competent authority of the member state validating the registration

7. Date 29/09/2025

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

ORGANON PHARMA (UK) LIMITED, SHOTTON LANE, CRAMLINGTON, NE23 3JU, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

Importation

3rd Country **Active Substance** 3rd Country Manufacturer Distributor

HYDROCHLOROTHIAZIDE IPCA LABORATORIES LIMITED, P.O. SEJAVTA, RATLAM, MADHYA (1000008764)PRADESH, IN-457001, INDIA

Issue Date: 29 Sep 2025 API Registration Number: UK API 25

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LOSARTAN POTASSIUM (2000007877) **DIVI'S LABORATORIES LIMITED**, UNIT 2, CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531 162, INDIA

ENALAPRIL MALEATE (2000007672)

SIEGFRIED EVIONNAZ SA, ROUTE DU SIMPLON 1,36, EVIONNAZ, CH-1902, SWITZERLAND

SITAGLIPTIN PHOSPHATE (2000010308)

MSD INTERNATIONAL GMBH, SINGAPORE BRANCH, 50 TUAS WEST DRIVE, SINGAPORE, SG-638408, SINGAPORE

ZHEJIANG TIANYU PHARMACEUTICAL CO., LTD., NO. 15 DONGHAI 5TH AVENUE, ZHEJIANG PROVINCIAL CHEMICAL AND MEDICAL RAW MATERIALS BASE, LINHAI ZONE, TAIZHOU CITY, ZHEJIANG PROVINCE, CN-317016, CHINA

MSD INTERNATIONAL GMBH, SINGAPORE BRANCH, 50 TUAS WEST DRIVE, SINGAPORE, SG-638408, SINGAPORE

MONTELUKAST SODIUM (2000007158)

EZETIMIBE (1000000757)

ZHEJIANG TIANYU PHARMACEUTICAL CO., LTD., NO. 15 DONGHAI 5TH AVENUE, ZHEJIANG PROVINCIAL CHEMICAL AND MEDICAL RAW MATERIALS BASE, LINHAI ZONE, TAIZHOU CITY, ZHEJIANG PROVINCE, CN-317016, CHINA

TEVA API INDIA PRIVATE LIMITED, PLOT NOS Q1 TO Q4, INDUSTRIAL ATORVASTATIN (1000008348) AREA, GHIRONGI, MALANPUR, BHIND, MADHYA PRADESH, IN-477 117, INDIA

MHRA: GMDY MHRA

Issue Date: 29 Sep 2025