

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 17661
2. Name or corporate name of registrant
PCCA LIMITED
3. Permanent or legal address of registrant
PCCA LIMITED, UNITS 1, 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place
PCCA LIMITED, UNITS 1, 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, 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
20/05/2025

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

PCCA LIMITED, UNITS 1, 2 AND 3 REGENTS DRIVE, LOW PRUDHOE INDUSTRIAL ESTATE, PRUDHOE, NE42 6PX, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

THYROID
1000007072

E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
NALTREXONE HYDROCHLORIDE (2000007614)	MALLINCKRODT CHEMICAL INCORPORATED , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
LIDOCAINE (1000015338)	SWATI SPENTOSE PRIVATE LIMITED , UNIT-I, PLOT NUMBER A-1/2102, 2103 AND A-2/2120, PHASE III, G.I.D.C., DISTRICT VALSAD, VAPI, GUJARAT, IN- 396195, INDIA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
PREGNENOLONE (1000011186)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES MEDISCA INC. , 6641 NORTH BELT LINE ROAD, UNIT 130, IRVING, 75063-6001, UNITED STATES
METHIMAZOLE (3000012191)	CHANGZHOU TIANHUA PHARMACEUTICAL CO LIMITED , NO. 3 HOUYANG CHEMICAL ZONE, GOLD TOWN, JINTAN, JIANGSU, CN-213200, CHINA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
ESTRADIOL (1000017043)	YICHENG GOTO PHARMACEUTICALS , GROUP 1 GAOKENG, XIAOHE, YICHENG, HUBEI PROVINCE, CN 441400, CHINA ZHEJIANG XIANJU PHARMA , NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG, CN-317300, CHINA QINHUANGDAO ZIZHU PHARMACEUTICAL COMPANY LIMITED , NO. 10 LONGHAI ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, QINHUANGDAO, HEBEI PROVINCE, CN-066 004, CHINA	MEDISCA PHARMACEUTIQUE INCORPORATION , 6090 HENRI BOURASSA BOULEVARD W, SAINT- LAURENT QC, H4R 3A6, CANADA PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

KETAMINE
HYDROCHLORIDE
(2000008609)

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

TRETINOIN (1000009303)

OLON SPA, VIA MILANO 186, GARBAGNATE MILANESE (MI), I-20024, ITALY

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

MELATONIN (1000000731)

SWATI SPENTOSE PRIVATE LIMITED, UNIT-I, PLOT NUMBER A-1/2102, 2103 AND A-2/2120, PHASE III, G.I.D.C., DISTRICT VALSAD, VAPI, GUJARAT, IN-396195, INDIA

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

LIOTHYRONINE SODIUM
(2000008504)

AZICO BIOPHORE INDIA PRIVATE LIMITED, PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531021, INDIA

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

THYROID (1000007072)

BIOIBERICA S.A.U, CARRER ANTIC CAMI DE TORDERA 109-119, PALAFOLLS, BARCELONA, E-08389, SPAIN

LEVOTHYROXINE SODIUM
(2000013292)

AZICO BIOPHORE INDIA PRIVATE LIMITED, PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531021, INDIA

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

EXCELLA GMBH & CO. KG, NUERNBERGER STRASSE 12, FEUCHT, D-90537, GERMANY

MEDISCA INC., 6641 NORTH BELT LINE ROAD, UNIT 130, IRVING, 75063-6001, UNITED STATES

TRAMADOL
HYDROCHLORIDE
(2000008034)

GVK BIOSCIENCES PRIVATE LIMITED, PLOT NO. 28A, IDA NACHARAM, HYDERABAD, TELANGANA, IN-500076, INDIA

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED, 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

CLIOQUINOL (1000004182)	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
ESTRIOL (3000004591)	QINHUANGDAO ZIZHU PHARMACEUTICAL COMPANY LIMITED , NO. 10 LONGHAI ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, QINHUANGDAO, HEBEI PROVINCE, CN-066 004, CHINA ZHEJIANG XIANJU PHARMACEUTICAL CO., LTD , NO. 15 WEST FENGXI ROAD, MODERN INDUSTRIAL PARK, XIANJU, TAIZHOU, ZHEJIANG, CN-317300, CHINA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
SODIUM VALPROATE (2000007475)	KATWIJK CHEMIE B.V. , SNIJDERSTRAAT 6, KATWIJK ZH, NL-2222 BA, NETHERLANDS PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TESTOSTERONE (1000009354)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
HYDROQUINONE (1000008752)	EASTMAN CHEMICAL COMPANY , 200 SOUTH WILCOX DRIVE, KINGSPORT, 37660, UNITED STATES	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
MIRTAZAPINE ANHYDROUS (2000014212)	MEDISCA PHARMACEUTIQUE INCORPORATION , 6090 HENRI BOURASSA BOULEVARD W, SAINT-LAURENT QC, H4R 3A6, CANADA	MEDISCA PHARMACEUTIQUE INCORPORATION , 6090 HENRI BOURASSA BOULEVARD W, SAINT-LAURENT QC, H4R 3A6, CANADA
FLUCONAZOLE (1000002222)	VIRUPAKSHA ORGANICS LIMITED , SURVEY NO 10, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, MEDAK DISTRICT, TELANGANA, IN-502 319, INDIA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

HYDROCORTISONE ACETATE (2000007338)	TIANJIN JINJIN PHARMACEUTICAL COMPANY LIMITED , 8 JINGFU ROAD, INDUSTRIAL ZONE OF ZHANGJIAWO TOWN, XIQING DISTRICT, TIANJIN, CN-300387, CHINA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TACROLIMUS MONOHYDRATE (2000016490)	BIOCON LIMITED , 20TH KM HOSUR ROAD, ELECTRONICS CITY, BANGALORE, IN-560 100, INDIA	BIOCON LIMITED , 20TH KM HOSUR ROAD, ELECTRONICS CITY, BANGALORE, IN-560 100, INDIA
PRASTERONE (1000006301)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
CANNABIDIOL (1000000540)	PURISYS LLC , 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES	PURISYS LLC , 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES
LOPERAMIDE HYDROCHLORIDE (2000008494)	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
SPIRONOLACTONE (1000009436)	ZHEJIANG LANGHUA PHARMACEUTICAL CO. LIMITED , ZHEJIANG PROVINCIAL CHEMICAL & MEDICAL MATERIALS BASE, LINHAI ZONE, LINHAI, ZHEJIANG PROVINCE, CN-317016, CHINA	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
CHLORAL HYDRATE (1000005193)	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
DRONABINOL (1000003105)	PURISYS LLC , 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES	PURISYS LLC , 1550 OLYMPIC DRIVE, ATHENS, 30601, UNITED STATES
BACLOFEN (1000009324)	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

HYDROCHLOROTHIAZIDE
(1000008764)

CHANGZHOU PHARMACEUTICAL FACTORY, 518
LAODONG EAST ROAD, CHANGZHOU, JIANGSU
PROVINCE, CN-213018, CHINA

**PROFESSIONAL COMPOUNDING
CENTERS OF AMERICA
INCORPORATED**, 9901 S. WILCREST
DRIVE, HOUSTON, 77099, UNITED
STATES

ENALAPRIL MALEATE
(2000007672)

NEULAND LABORATORIES LIMITED, UNIT 1,
SURVEY NO. 347, 473, 474, 490/2,
VEERABHADRASWAMY TEMPLE ROAD,
BONTHAPALLI VILLAGE, GUMMADIDALA MANDAL,
SANGAREDDY DISTRICT, TELANGANA, IN 502313,
INDIA

**PROFESSIONAL COMPOUNDING
CENTERS OF AMERICA
INCORPORATED**, 9901 S. WILCREST
DRIVE, HOUSTON, 77099, UNITED
STATES

PROGESTERONE
(1000009777)

**JIANGSU JIAERKE PHARMACEUTICALS GROUP
CORP**, SANHUANGMIAO, WUJIN, CHANGZHOU,
ZHENGLU, JIANGSU, CN-213 111, CHINA

**PROFESSIONAL COMPOUNDING
CENTERS OF AMERICA
INCORPORATED**, 9901 S. WILCREST
DRIVE, HOUSTON, 77099, UNITED
STATES

CANNABIS FLOWER
(4000016460)

CASTLE ROCK FARMS INC (BC GREEN), 253
DAVID BROWN WAY, Data Not Available,
PRINCETON BC, V0X 1W0, CANADA

**CASTLE ROCK FARMS INC (BC
GREEN)**, 253 DAVID BROWN WAY, Data
Not Available, PRINCETON BC, V0X
1W0, CANADA

RASAGILINE MESYLATE
(2000005590)

GLENMARK PHARMACEUTICALS LIMITED, PLOT
NO. 3109, G.I.D.C. INDUSTRIAL ESTATE,
ANKLESHWAR, BHARUCH DISTRICT, GUJARAT, IN
393002, INDIA

**GLENMARK PHARMACEUTICALS
LIMITED**, PLOT NO. 3109, G.I.D.C.
INDUSTRIAL ESTATE, ANKLESHWAR,
BHARUCH DISTRICT, GUJARAT, IN
393002, INDIA

TRIAMCINOLONE 21-
ACETATE (2000003684)

NEWCHEM S.P.A., VIA ROVEGGIA 47, VERONA, I-
37136, ITALY

**PROFESSIONAL COMPOUNDING
CENTERS OF AMERICA
INCORPORATED**, 9901 S. WILCREST
DRIVE, HOUSTON, 77099, UNITED
STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 THYROID (1000007072)