

# 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   | 10/06/2024   |

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
LEVOTHYROXINE SODIUM (2000013292)	<b>EXCELLA GMBH &amp; CO. KG</b> , NUERNBERGER STRASSE 12, FEUCHT, D-90537, GERMANY	<b>MEDISCA INC.</b> , 6641 NORTH BELT LINE ROAD, UNIT 130, IRVING, 75063-6001, UNITED STATES
ENALAPRIL MALEATE (2000007672)	<b>NEULAND LABORATORIES LIMITED</b> , UNIT 1, SURVEY NO. 347, 473, 474, 490/2, VEERABHADRASWAMY TEMPLE ROAD, BONTAPALLI VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN 502313, INDIA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
ESTRADIOL (1000017043)	<b>ZHEJIANG XIANJU PHARMA</b> , NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG, CN-317300, CHINA <b>QINHUANGDAO ZIZHU PHARMACEUTICAL COMPANY LIMITED</b> , NO. 10 LONGHAI ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, QINHUANGDAO, HEBEI PROVINCE, CN-066004, CHINA <b>YICHENG GOTO PHARMACEUTICALS</b> , GROUP 1 GAOKENG, XIAOHE, YICHENG, HUBEI PROVINCE, CN 441400, CHINA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES <b>MEDISCA PHARMACEUTIQUE INCORPORATION</b> , 6090 HENRI BOURASSA BOULEVARD W, SAINT-LAURENT QC, H4R 3A6, CANADA
CHLORAL HYDRATE (1000005193)	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
SODIUM VALPROATE (2000007475)	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES <b>KATWIJK CHEMIE B.V.</b> , SNIJDERSTRAAT 6, KATWIJK ZH, NL-2222 BA, NETHERLANDS	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 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

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

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

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

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

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

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

HYDROCORTISONE ACETATE (2000007338)	<b>TIANJIN JINJIN PHARMACEUTICAL COMPANY LIMITED</b> , 8 JINGFU ROAD, ZHANGJIAWO TOWN INDUSTRIAL ZONE, XIQING DISTRICT ECONOMIC AND DEVELOPMENT AREA, ZHANGJIAWO, TIANJIN, CN-300380, CHINA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
BACLOFEN (1000009324)	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
LOPERAMIDE HYDROCHLORIDE (2000008494)	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TRIAMCINOLONE 21- ACETATE (2000003684)	<b>NEWCHEM S.P.A.</b> , VIA ROVEGGIA 47, VERONA, I-37136, ITALY	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
TRETINOIN (1000009303)	<b>OLON SPA</b> , VIA MILANO 186, GARBAGNATE MILANESE (MI), I-20024, ITALY	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
PROGESTERONE (1000009777)	<b>JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP</b> , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA  <b>PHARMACIA &amp; UPJOHN COMPANY LLC</b> , 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
METHIMAZOLE (3000012191)	<b>CHANGZHOU TIANHUA PHARMACEUTICAL CO LIMITED</b> , NO. 3 HOUYANG CHEMICAL ZONE, GOLD TOWN, JINTAN, JIANGSU, CN-213200, CHINA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES

ESTRIOL (3000004591)	<b>QINHUANGDAO ZIZHU PHARMACEUTICAL COMPANY LIMITED</b> , NO. 10 LONGHAI ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, QINHUANGDAO, HEBEI PROVINCE, CN-066004, CHINA  <b>ZHEJIANG XIANJU PHARMA</b> , NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG, CN-317300, CHINA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
NALTREXONE HYDROCHLORIDE (2000007614)	<b>MALLINCKRODT CHEMICAL INCORPORATED</b> , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
CLIOQUINOL (1000004182)	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
PRASTERONE (1000006301)	<b>JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP</b> , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
HYDROCHLOROTHIAZIDE (1000008764)	<b>CHANGZHOU PHARMACEUTICAL FACTORY</b> , 518 LAODONG EAST ROAD, CHANGZHOU, JIANGSU PROVINCE, CN-213018, CHINA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
FLUCONAZOLE (1000002222)	<b>VIRUPAKSHA ORGANICS LIMITED</b> , SURVEY NO 10, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, MEDAK DISTRICT, TELANGANA, IN-502 319, INDIA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 9901 S. WILCREST DRIVE, HOUSTON, 77099, UNITED STATES
LIOTHYRONINE SODIUM (2000008504)	<b>AZICO BIOPHORE INDIA PRIVATE LIMITED</b> , PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531021, INDIA	<b>PROFESSIONAL COMPOUNDING CENTERS OF AMERICA INCORPORATED</b> , 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

TACROLIMUS **BIOCON LIMITED**, 20TH KM HOSUR ROAD,  
MONOHYDRATE ELECTRONICS CITY, BANGALORE, IN-560 100,  
(2000016490) INDIA

**BIOCON LIMITED**, 20TH KM HOSUR  
ROAD, ELECTRONICS CITY,  
BANGALORE, IN-560 100, INDIA

SPIRONOLACTONE **ZHEJIANG LANGHUA PHARMACEUTICAL CO.**  
(1000009436) **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

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution  
THYROID (1000007072)