

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 1375 |
| 2. Name or corporate name of registrant | R W UNWIN & COMPANY LIMITED |
| 3. Permanent or legal address of registrant | R W UNWIN & COMPANY LIMITED, MANSELLS FARM, HITCHIN ROAD, CODICOTE, HITCHIN, SG4 8TJ, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | R W UNWIN & CO LTD, MANSELLS FARM, HITCHIN ROAD, CODICOTE, HITCHIN, SG4 8TJ, 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 | 20/11/2023 |

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

R W UNWIN & CO LTD, MANSELLS FARM, HITCHIN ROAD, CODICOTE, HITCHIN, SG4 8TJ, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
PRASTERONE (1000006301)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP., SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	MEDISCA, 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
NIACINAMIDE (4000009993)	TIANJIN ZHONGRUI PHARMACEUTICAL CO LIMITED, EASTERN BEIHUAN ROAD, CHENGGUAN TOWN, WUQING DISTRICT, TIANJIN CITY, CN-301712, CHINA	MEDISCA, 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES

BUTYLATED HYDROXYTOLUENE (1000008611)	PENTA INTERNATIONAL CORP. , 50 OKNER PARKWAY, LIVINGSTON, 07039-1604, UNITED STATES	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
CHLORPHENAMINE MALEATE (4000007290)	KONGO CHEMICAL COMPANY LIMITED , NO 3 HIMATA, TOYAMA, JP-930-0912, JAPAN	
SODIUM SALICYLATE (2000007480)	JQC (HUAYIN) PHARMACEUTICAL COMPANY LIMITED , YUQUAN ROAD, HUAYIN CITY, SHAANXI, CN-714203, CHINA	
TACROLIMUS (1000002882)	BIOCON , BIOCON HOUSE, SEMICON PARK, 1ST FLOOR, ELECTRONICS CITY PHASE 2, BANGALORE, IN- 560100, INDIA	
ESTRADIOL VALERATE (2000016109)	ZHEJIANG XIANJU PHARMACEUTICAL CO LIMITED , NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG, CN-317300, CHINA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
FOLIC ACID (1000001996)	DSM NUTRITIONAL PRODUCTS AG , ZWEIGNIEDERLASSUNG WERK SISSELN, HAUPSTRASSE 4, SISSELN, CH-43334, SWITZERLAND	
OMEPRAZOLE (1000009101)	EVEREST ORGANICS LIMITED , LAKEVIEW PLAZA PLOT NO. 127 & 128, AMAR CO-OP. SOCIETY, NEAR DURGAMCHERVU, MADHAPUR, HYDERABAD, TELANGANA, IN-500 033, INDIA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
TETRACAINE (1000012475)	VENKATA NARAYANA ACTIVE INGREDIENTS PRIVATE LIMITED (FORMERLY NUTRA SPECIALITIES PRIVATE LIMITED) , VENKATA NARAYANA TOWERS, 3RD FLOOR, NEW NO 60, OLD NO 35 VENKATA NARAYANA ROAD, THEAGARAYA NAGAR, CHENNAI, TAMIL NADU, IN-600017, INDIA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)	MALLADI DRUGS & PHARMACEUTICALS LIMITED , 9 GST ROAD, ST THOMAS MOUNT, CHENNAI, IN-600 016, INDIA	
TOPIRAMATE (1000002932)	BIOCON , BIOCON HOUSE, SEMICON PARK, 1ST FLOOR, ELECTRONICS CITY PHASE 2, BANGALORE, IN- 560100, INDIA	OCEANIC PHARMACHEM , 329 A-Z INDUSTRIAL ESTATE, G.KADAM MARG, LOWER PAREL, MUMBAI, IN- 400 013, INDIA

ZOPICLONE (1000009091)	CENTAUR PHARMACEUTICALS PRIVATE LIMITED , PLOT NO 75, 76 & 76/1, CHIKHLOLI MIDC, AMBERNATH (WEST), THANE, MAHARASHTRA, IN-421 501, INDIA	
SIROLIMUS (1000008469)	BIOCON , BIOCON HOUSE, SEMICON PARK, 1ST FLOOR, ELECTRONICS CITY PHASE 2, BANGALORE, IN- 560100, INDIA	
HYDROQUINONE (1000008752)	MEDILUX LABORATORIES PVT LIMITED , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
TRANEXAMIC ACID (1000009308)	HUNAN DONGTING, PHARMACEUTICAL CO. LIMITED , NO.16 DONGYANG ROAD, CHENJIAGANG COMMUNITY, DESHAN SUB-DISTRICT OFFICE, CHANGDE ECONOMIC AND TECHNICAL DEVELOPMENT ZONE, CHANGDE CITY, HUNAN PROVINCE, CN-415001, CHINA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
BETAMETHASONE VALERATE (2000008358)	SYMBIOTICA , NO. 518 JALAN WAJA 4, WAJA INDUSTRIAL ESTATE, KULIM, KEDAH, MY-09000, MALAYSIA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
7-KETO-DHEA (3000019722)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP. , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
SODIUM CYCLAMATE (1000008715)	ZHONG HUA FANG DA (H.K) LIMITED , YANGQUAN ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, DALIAN ROAD, SHANXI, CN-045000, CHINA	
BANANA FLAVOUR (1000006200)	FLAVORX , 9475 GERWIG LANE, COLUMBIA, 21046, UNITED STATES	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
PHENYLEPHRINE BITARTRATE (4000007411)	MALLADI DRUGS & PHARMACEUTICALS LIMITED , 9 GST ROAD, ST THOMAS MOUNT, CHENNAI, IN-600 016, INDIA	
SIMVASTATIN (1000009116)	BIOCON , BIOCON HOUSE, SEMICON PARK, 1ST FLOOR, ELECTRONICS CITY PHASE 2, BANGALORE, IN- 560100, INDIA	
VANILLIN (1000008735)	SOLVAY USA INC , 1275 AIRLINE HIGHWAY, BATON ROUGE, 70805-1002, UNITED STATES	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES

AMLODIPINE BESILATE (2000015864)	MALLADI DRUGS & PHARMACEUTICALS LIMITED , 9 GST ROAD, ST THOMAS MOUNT, CHENNAI, IN-600 016, INDIA	
ESTRADIOL HEMIHYDRATE (2000016108)	ZHEJIANG XIANJU PHARMACEUTICAL CO LIMITED , NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG, CN-317300, CHINA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
ZINC SULPHATE MONOHYDRATE (4000010708)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP. , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
CLINDAMYCIN PHOSPHATE (2000008016)	ZHEJIANG Tiantai PHARMACEUTICAL CO. LIMITED , 588 FENGZE ROAD, TAIZHOU CITY, Tiantai COUNTY, ZHEJIANG PROVINCE, CN-317200, CHINA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
PHENYLEPHRINE (1000009891)	MALLADI DRUGS & PHARMACEUTICALS LIMITED , 9 GST ROAD, ST THOMAS MOUNT, CHENNAI, IN-600 016, INDIA	
PREGNENOLONE (1000011186)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP. , SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	MEDISCA , 661 ROUTE 3, UNIT C, PLATTSBURGH, 12901, UNITED STATES
PROTAMINE SULPHATE (4000010193)	YUKI GOSEI KOGYO COMPANY LIMITED , 788 OCHIAI, JOBAN NISHIGO-MACHI, IWAKI-SHI, FUKUSHIMA PREFECTURE, JP- 972-8316, JAPAN	
PILOCARPINE (1000009876)	SOURCETECH QUIMICA LIMITADA , RUA SUICA 3430, PINDAMONHANGABA-SP, BR-12403 610, BRAZIL	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	ZINC PYRITHIONE (4000008930)
	PREDNISOLONE SODIUM PHOSPHATE (2000007914)
	PRASTERONE (1000006301)
	CLONAZEPAM (1000004077)
	ISOSORBIDE-5-MONONITRATE DILUTED IN LACTOSE 80/20 (4000013959)
	ISOSORBIDE-5-MONONITRATE DILUTED IN LACTOSE 25/75 (4000013958)
	LEVOTHYROXINE SODIUM (2000013292)
	DISOPYRAMIDE PHOSPHATE (2000007751)
	FENOFIBRATE (1000002301)
	LIDOCAINE HYDROCHLORIDE (2000014083)
	PROGESTERONE (1000009777)
	NIACINAMIDE (4000009993)

IMIPRAMINE PAMOATE (2000016944)
D-BIOTIN (3000009891)
CHLOROTHIAZIDE (1000004605)
ISOSORBIDE 5-MONONITRATE (4000006581)
CARBAMAZEPINE (1000006757)
TRIAMTERENE (1000009300)
BUTYLATED HYDROXYTOLUENE (1000008611)
METRONIDAZOLE BENZOATE (2000008258)
MEDROXYPROGESTERONE ACETATE (2000008411)
CHLORPHENAMINE MALEATE (4000007290)
BISOPROLOL FUMARATE (2000008290)
ESOMEPRAZOLE SODIUM (2000006223)
NITROFURANTOIN (1000009675)
DISODIUM CLODRONATE (4000002029)
BENPERIDOL (1000009246)
AMILORIDE HYDROCHLORIDE (2000008529)
CYCLOSPORINE (3000005991)
IBUPROFEN LYSINATE (4000009786)
SODIUM SALICYLATE (2000007480)
BENZOYL PEROXIDE (1000009105)
CLOMIPRAMINE HYDROCHLORIDE (2000008121)
NALTREXONE BASE (3000019121)
LOPERAMIDE HYDROCHLORIDE (2000008494)
KETAMINE HYDROCHLORIDE (2000008609)
KETAZOLAM (1000008510)
HYDROCORTISONE SODIUM SUCCINATE (2000007334)
PIROXICAM (1000009856)
PINDOLOL (1000009872)
ADAPALENE (1000002293)
TESTOSTERONE PROPIONATE (2000007380)
NALOXONE HYDROCHLORIDE (2000008238)
CODEINE HYDROBROMIDE (2000016937)
KETOPROFEN LYSINATE (2000015216)
ETHOSUXIMIDE (1000002600)
TACROLIMUS (1000002882)
ISOTRETINOIN (1000008223)
AMLODIPINE (1000009119)
ESTRADIOL VALERATE (2000016109)
METAMPHETAMINE HYDROCHLORIDE (2000009441)
GLYCOPYRROLATE (4000009718)
QUETIAPINE FUMARATE (2000005649)

OXYBUTYNIN HYDROCHLORIDE (2000008318)
DEXAMETHASONE (1000003334)
FINASTERIDE (1000007415)
METRONIDAZOLE (1000001131)
NITRAZEPAM (1000009676)
TOLTERODINE TARTRATE (2000013355)
CLONIDINE HYDROCHLORIDE (2000008010)
TIZANIDINE HYDROCHLORIDE (2000008572)
RIFAMPICIN (1000009725)
GLYCINE (1000012477)
AMINOSALICYLIC ACID (1000008930)
BENZBROMARONE (1000003448)
CYPROTERONE ACETATE (2000007860)
PERPHENAZINE (1000009586)
ADRENALINE TARTRATE (4000006411)
ALIMEMAZINE TARTRATE (4000006319)
RANITIDINE HYDROCHLORIDE (2000007813)
DIHYDROCODEINE (1000003082)
CHLORTALIDONE (3000004761)
BOSENTAN MONOHYDRATE (2000005705)
CAFFEINE ANHYDROUS (3000005457)
GLYCERINE (3000000199)
TRIHEXYPHENIDYL HYDROCHLORIDE (4000006899)
TESTOSTERONE (1000009354)
TIZANIDINE (1000007875)
PERPHENAZINE ENANTATE (2000015324)
KETOPROFEN (1000008346)
ISOSORBIDE-5-MONONITRATE DILUTED IN LACTOSE 40/60 (4000013961)
LOTEPREDNOL ETABONATE (2000006253)
ISOSORBIDE DINITRATE IN LACTOSE MIXTURE 25:75% (4000008090)
IBUPROFEN SODIUM (2000011939)
FOLIC ACID (1000001996)
CHLORDIAZEPOXIDE (1000004715)
DICYCLOMINE HYDROCHLORIDE (2000007772)
BROMAZEPAM (1000007272)
NALTREXONE HYDROCHLORIDE (2000007614)
OMEPRazole (1000009101)
BACLOFEN (1000009324)
SPIRONOLACTONE (1000009436)
OXCARBAZEPINE (1000003329)
LORAZEPAM (1000008543)

MINOXIDIL (1000000832)
CHOLESTEROL POWDER (3000021666)
MEMANTINE HYDROCHLORIDE (2000006625)
TETRACAINE (1000012475)
BIOTIN (1000007405)
MORPHINE HYDROCHLORIDE (2000008247)
PENTAZOCINE (1000009591)
DIAZEPAM (1000003208)
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)
BUSULFAN (3000005691)
PROPRANOLOL HYDROCHLORIDE (2000007892)
TRIMEPRAZINE TARTRATE (2000008580)
HYDROCORTISONE ACETATE (2000007338)
HYDROCORTISONE (1000008762)
ISOSORBIDE-5-MONONITRATE DILUTED IN LACTOSE 90/10 (4000013960)
BENDAMUSTINE HYDROCHLORIDE (2000006919)
TOPIRAMATE (1000002932)
PENTAZOCINE HYDROCHLORIDE (2000008082)
PROCHLORPERAZINE MALEATE (2000007903)
PERPHENAZINE DECANOATE (2000015323)
ZOPICLONE (1000009091)
NITROFURANTOIN MONOHYDRATE (2000009285)
SIROLIMUS (1000008469)
HYDROQUINONE (1000008752)
TEMAZEPAM (1000009363)
BENDROFLUMETHIAZIDE (3000006463)
DEXAMPHETAMINE SULPHATE (2000007842)
DOTHIEPIN HYDROCHLORIDE (4000013248)
TRANEXAMIC ACID (1000009308)
TESTOSTERONE MICRONISED (2000018723)
SELEGILINE HYDROCHLORIDE (2000007734)
MERCAPTOPYRINE (1000000947)
PHOLCODINE (1000009886)
TOLAZAMIDE (1000009316)
OXAZEPAM (1000009641)
AMPHETAMINE SULPHATE (2000010810)
BETAMETHASONE VALERATE (2000008358)
DIPYRIDAMOLE (1000002962)
CLOBAZAM (1000004171)
RAMIPRIL (1000009080)
TESTOSTERONE ENANTATE (4000006624)

DIETHYLPROPION HYDROCHLORIDE (2000007770)
TAMOXIFEN CITRATE (2000007386)
7-KETO-DHEA (3000019722)
AZATHIOPRINE (1000009761)
TRANLYCYPROMINE SULPHATE (2000008589)
METHADONE HYDROCHLORIDE (2000008337)
SODIUM CYCLAMATE (1000008715)
METHADONE (1000000638)
ZONISAMIDE (1000003230)
ISOSORBIDE DINITRATE (2000008057)
CHLORAL HYDRATE (1000005193)
GUANIDINE NITRATE (2000018151)
BANANA FLAVOUR (1000006200)
CODEINE PHOSPHATE HEMIHYDRATE (4000006570)
AMILORIDE HYDROCHLORIDE DIHYDRATE (4000006310)
PHENYLEPHRINE BITARTRATE (4000007411)
IOHEXOL (1000007901)
ACYCLOVIR (1000007387)
SIMVASTATIN (1000009116)
PROMAZINE HYDROCHLORIDE (2000007897)
ESOMEPRAZOLE MAGNESIUM (2000006165)
OXYBUTYNIN (1000009086)
FUROSEMIDE (3000005943)
SELENIUM SULFIDE (3000010141)
DANAZOL (1000003803)
FINASTERIDE MICRONISED (2000018155)
DILTIAZEM HYDROCHLORIDE (2000007763)
TRAMADOL (1000007320)
BETAHISTINE DIHYDROCHLORIDE (4000007579)
DICLOFENAC FREE ACID (3000008741)
BUPIVACAINE HYDROCHLORIDE (2000008278)
DEQUALINIUM CHLORIDE (2000007849)
METOPROLOL TARTRATE (2000008259)
TRIFLUOPERAZINE HYDROCHLORIDE (2000008581)
VANILLIN (1000008735)
DICLOFENAC SODIUM (2000007774)
CHLORDIAZEPOXIDE HYDROCHLORIDE (2000008104)
TESTOSTERONE CIPIONATE (2000015349)
PERAZINE DIMALONATE (2000014601)
AMLODIPINE BESILATE (2000015864)
DICLOFENAC POTASSIUM (2000005773)

PROCHLORPERAZINE (1000009780)
METFORMIN HYDROCHLORIDE (2000008338)
ESTRADIOL HEMIHYDRATE (2000016108)
CLIDINIUM BROMIDE (2000008018)
NEOMYCIN SULPHATE (2000008175)
OXYCODONE HYDROCHLORIDE (2000006722)
IMIPRAMINE HYDROCHLORIDE (2000007321)
ESOMEPRAZOLE (1000000848)
ZINC SULPHATE MONOHYDRATE (4000010708)
PROCYCLIDINE HYDROCHLORIDE (2000007901)
SILDENAFIL CITRATE (2000006954)
LIDOCAINE BASE (3000009760)
AZELAIC ACID (1000007411)
CLOTRIMAZOLE (1000003999)
ESTRADIOL BENZOATE (2000016107)
MORPHINE SULPHATE (2000008246)
CLINDAMYCIN PHOSPHATE (2000008016)
MONOPROPYLENE GLYCOL (3000001144)
NIFEDIPINE (1000009680)
BENAZEPRIL HYDROCHLORIDE (2000006111)
ZINC SULFATE (4000006810)
PHENYLEPHRINE (1000009891)
ACETAZOLAMIDE (1000002240)
PHENYTOIN BASE (2000019342)
PREGNENOLONE (1000011186)
NIMODIPINE (1000009678)
SODIUM CROMOGLICATE (4000007084)
THIORIDAZINE HYDROCHLORIDE (2000008605)
INDOMETHACIN (1000008682)
PROTAMINE SULPHATE (4000010193)
AMITRIPTYLINE HYDROCHLORIDE (2000008522)
MEPIVACAINE HYDROCHLORIDE (2000008341)
MIDAZOLAM (1000000928)
PROCHLORPERAZINE EDISYLATE (2000016947)
NITROFURANTOIN MACROCRYSTALS (3000007709)
TRETINOIN (1000009303)
DIHYDROCODEINE TARTRATE (2000007767)
PILOCARPINE (1000009876)
ORPHENADRINE HYDROCHLORIDE (2000008157)