

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 4351
2. Name or corporate name of registrant	PENN PHARMACEUTICAL SERVICES LIMITED
3. Permanent or legal address of registrant	PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, 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	03/06/2024

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

PENN PHARMACEUTICAL SERVICES LIMITED, UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
POMALIDOMIDE (1000016945)	CARBOGEN AMCIS , HAUPTSTRASSE 171, BUBENDORF, CH-4416, SWITZERLAND	

MENADIOL DIPHOSPHATE (2000020237)	API INCORPORATED , 10 INDUSTRIAL ROAD, FAIRFIELD, 07004, UNITED STATES	SHANGHAI WANSU PHARMACEUTICAL CO , NO DATA HELD, Data Not Available, Data Not Available, JAPAN
ISOCARBOXAZID (1000008028)	API INCORPORATED , 10 INDUSTRIAL ROAD, FAIRFIELD, 07004, UNITED STATES	SHANGHAI WANSU PHARMACEUTICAL CO , NO DATA HELD, Data Not Available, Data Not Available, JAPAN
IBANDRONATE MONOSODIUM MONOHYDRATE (4000014459)	F. HOFFMANN-LA ROCHE LIMITED , GRENZACHERSTRASSE 124, BASEL, CH-4070, SWITZERLAND	
MACITENTAN MICRONISED (2000018968)	LONZA AG , ROTTENSTRASSE 6, VISP, CH-3930, SWITZERLAND	LONZA AG , ROTTENSTRASSE 6, VISP, CH- 3930, SWITZERLAND
ONDANSETRON (1000009100)	PLOT NO. D-7, M.I.D.C. INDUSTRIAL AREA , PLOT NO. D-7, M.I.D.C. INDUSTRIAL AREA, KURKUMBH VILLAGE, TALUKA DAUND, DISTRICT PUNE, IN 413802, INDIA	
TEMOZOLOMIDE (1000002416)	FORMOSA LABORATORIES INC , 36 HOPING STREET, LOUCHU TOWNSHIP, TAOYUAN COUNTY, TW 33842, TAIWAN	FORMOSA LABORATORIES INC , 36 HOPING STREET, LOUCHU TOWNSHIP, TAOYUAN COUNTY, TW 33842, TAIWAN
VANDETANIB (1000011523)	LONZA AG , LONZASTRASSE 2, VISP, CH-3930, SWITZERLAND	LONZA AG , LONZASTRASSE 2, VISP, CH-3930, SWITZERLAND
THALIDOMIDE (1000007423)	SIEGFRIED AG , UNTERE BRUEHLSTRASSE 4, ZOFINGEN, CH-4800, SWITZERLAND	SIEGFRIED AG , UNTERE BRUEHLSTRASSE 4, ZOFINGEN, CH-4800, SWITZERLAND
TADALAFIL (1000000162)	SMS PHARMACEUTICALS LIMITED , UNIT II PLOT NO. 24 AND 24B, SV.CO-OPERATIVE INDUSTRIAL ESTATE, BACHUPALLY, MEDCHAL-MALKAJGIRI DISTRICT, HYDERABAD, TELANGANA, IN-500 090, INDIA	SMS PHARMACEUTICALS LIMITED , UNIT II PLOT NO. 24 AND 24B, SV.CO-OPERATIVE INDUSTRIAL ESTATE, BACHUPALLY, MEDCHAL-MALKAJGIRI DISTRICT, HYDERABAD, TELANGANA, IN-500 090, INDIA
IBANDRONATE (3000022303)	MAPRIMED SA , CORONEL PRUDENCIO MURGUIONDO 2011, BUENOS AIRES, AR-1440, ARGENTINA	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 THALIDOMIDE (1000007423)

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