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 4
2. Name or corporate name of registrant	GLAXO OPERATIONS UK LIMITED
3. Permanent or legal address of registrant	GLAXO OPERATIONS UK LIMITED, 79 NEW OXFORD STREET, LONDON, WC1A 1DG, UNITED KINGDOM
	GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	GLAXOSMITHKLINE, COBDEN STREET, MONTROSE, DD10 8EA, UNITED KINGDOM
	GLAXO OPERATIONS UK LTD (WARE) T\A GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, 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	30/10/2026

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

GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
HYDROUS BENZOYL PEROXIDE (2000007330)	**ARKEMA INC.**, 3289 GENESEE STREET, PIFFARD, 14533, UNITED STATES	

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CABOTEGRAVIR (1000017903)	**N.V.AJINOMOTO OMNICHEM**, COOPPALLAAN 91, WETTEREN, B-9230, BELGIUM **GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
HYDROCORTISONE (1000008762)	**PHARMACIA & UPJOHN (PFIZER GLOBAL MANUFACTURING)**, 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES	
CLINDAMYCIN PHOSPHATE (2000008016)	**ZHEIJANG HISOAR PHARMACEUTICAL CO LIMITED**, 1 HAIZHENG AVENUE, JIAOJIANG DISTRICT, TAIZHOU CITY, CN-318000, CHINA **ZHEJIANG HISOAR PHARMACEUTICAL CO. LIMITED**, NO. 23, 5TH DONGHAI AVENUE, ZHEJIANG CHEMICAL MATERIALS BASE LINHAI ZONE, LINHAI CITY, ZHEJIANG PROVINCE, CN-317016, CHINA	
FLUTICASONE PROPIONATE (2000008220)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
ZANAMIVIR (1000000992)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
SUMATRIPTAN SUCCINATE (2000008222)	**DIVIS LABORATORIES LIMITED, UNIT 2 CHIPPADA VILLAGE**, UNIT 2 CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM DISTRICT, ANDHRA PRADESH, IN-531162, INDIA	
ZIDOVUDINE (1000009208)	**APITORIA PHARMA PRIVATE LIMITED**, UNIT-II, SURVEY NO. 10 & 13, IDA, KAZIPALLY, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN-502319, INDIA	
BEPIROVIRSEN (3000020981)	**WUXI STA PHARMACEUTICAL CO., LIMITED.**, 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, JIANGSU, CN-213127, CHINA	**NITTO DENKO AVECIA INC.**, 125 FORTUNE BOULEVARD, MILFORD, 01757, UNITED STATES

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ACICLOVIR (3000006349)	**MATRIX PHARMACORP PRIVATE LIMITED (UNIT 2)**, C/O MATRIX PHARMACORP PRIVATE LIMITED, (UNIT 2), SURVEY NO. 10/42, GADDAPOTHARAM, KAZIPALLY INDUSTRIAL AREA, TELANGANA, SANGAREDDY DISTRICT, IN-502319, INDIA
FLUTICASONE FUROATE (2000014516)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FLUTICASONE PROPIONATE (2000008220)

ZANAMIVIR (1000000992)

ZIDOVUDINE (1000009208)

FLUTICASONE FUROATE (2000014516)

Name and address of the site

GLAXOSMITHKLINE, COBDEN STREET, MONTROSE, DD10 8EA, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

CLOBETASONE BUTYRATE

2000008013

F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

DUTASTERIDE

1000007791

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging

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F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
SALBUTAMOL SULPHATE
2000007742

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Sulphate salt formation and crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
UMECLIDINIUM BROMIDE
4000014045

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
BETAMETHASONE VALERATE

MHRA-GMDP MHRA

2000008358

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, micronisation.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FLUTICASONE PROPIONATE

2000008220

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

VILANTEROL TRIFENATATE

4000013535

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates

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	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

CLOBETASOL PROPIONATE

2000008014

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

ZANAMIVIR

1000000992

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation

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E	General Finishing Steps
	E.1 Physical Processing Steps Rehumidification, Blending, Sieving
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

ABACAVIR SULPHATE

2000005612

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation and salt formation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FLUTICASONE FUROATE

2000014516

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying

MHRA-GMDP MHRA

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
ROPINIROLE
1000003050

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Re-crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance
LACIDIPINE
1000007375

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging

MHRA-GMDP MHRA

F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
CLOBETASONE BUTYRATE (2000008013)	**SYMBIOTEC PHARMALAB PVT LIMTED**, PLOT NO. 385/2 PIGDAMBER, NEAR HOTEL MASHAL, OFF A B ROAD, RAU, INDORE DISTRICT, MADHYA PRADESH, IN-453331, INDIA	
CLOBETASOL PROPIONATE (2000008014)	**SYMBIOTEC PHARMALAB PVT LIMTED**, PLOT NO. 385/2 PIGDAMBER, NEAR HOTEL MASHAL, OFF A B ROAD, RAU, INDORE DISTRICT, MADHYA PRADESH, IN-453331, INDIA	
ABACAVIR SULPHATE (2000005612)	**PIRAMAL ENTERPRISES LIMITED**, SURVEY NOS. 7-70, 70/1 AND 70/2, DIGWAL VILLAGE, KOHIR MANDAL, KOHIR CROSS ROAD, SANGAREDDY DISTRICT, TELANGANA, IN-502321, INDIA	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

CLOBETASONE BUTYRATE (2000008013)

DUTASTERIDE (1000007791)

SALBUTAMOL SULPHATE (2000007742)

UMECLIDINIUM BROMIDE (4000014045)

BETAMETHASONE VALERATE (2000008358)

FLUTICASONE PROPIONATE (2000008220)

VILANTEROL TRIFENATATE (4000013535)

CLOBETASOL PROPIONATE (2000008014)

ZANAMIVIR (1000000992)

ABACAVIR SULPHATE (2000005612)

FLUTICASONE FUROATE (2000014516)

ROPINIROLE (1000003050)

LACIDIPINE (1000007375)

Name and address of the site

GLAXO OPERATIONS UK LTD (WARE) T\A GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
FLUTICASONE FUROATE
2000014516

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E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

SALMETEROL XINAFOATE

2000008392

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

DOLUTEGRAVIR SODIUM

4000014056

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation for GW Manufacturing and Shanghai Desano Chemical
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FLUTICASONE PROPIONATE

2000008220

MHRA-GMDP MHRA

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CABOTEGRAVIR SODIUM

2000017021

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

UMECLIDINIUM BROMIDE

4000014045

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VILANTEROL TRIFENATATE

4000013535

MHRA-GMDP MHRA

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
FLUTICASONE FUROATE (2000014516)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
SALMETEROL XINAFOATE (2000008392)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
DOLUTEGRAVIR SODIUM (4000014056)	**SHANGHAI DESANO CHEMICAL PHARMACEUTICAL COMPANY LIMITED**, 417 BINHAI ROAD, LAOGANG TOWN, PUDONG NEW AREA, SHANGHAI, CN 201302, CHINA **SHIONOGI PHARMACHEMICALS CO. LIMITED**, 224-20, HIRAISHIEBISUNO, KAWAUCHI-CHO, TOKUSHIMA, JP 771-0132, JAPAN **GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE
ZIDOVUDINE (1000009208)	**APITORIA PHARMA PRIVATE LIMITED**, UNIT-II, SURVEY NO. 10 & 13, IDA, KAZIPALLY, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN-502319, INDIA	
FLUTICASONE PROPIONATE (2000008220)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	

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DAPRODUSTAT (3000018715)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
CABOTEGRAVIR SODIUM (2000017021)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
LAMIVUDINE (1000003255)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE **MATRIX PHARMACORP PRIVATE LIMITED (UNIT 2)**, C/O MATRIX PHARMACORP PRIVATE LIMITED, (UNIT 2), SURVEY NO. 10/42, GADDAPOTHARAM, KAZIPALLY INDUSTRIAL AREA, TELANGANA, SANGAREDDY DISTRICT, IN-502319, INDIA	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE **MATRIX PHARMACORP PRIVATE LIMITED (UNIT 2)**, C/O MATRIX PHARMACORP PRIVATE LIMITED, (UNIT 2), SURVEY NO. 10/42, GADDAPOTHARAM, KAZIPALLY INDUSTRIAL AREA, TELANGANA, SANGAREDDY DISTRICT, IN-502319, INDIA
UMECLIDINIUM BROMIDE (4000014045)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
PAZOPANIB (1000011372)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
VILANTEROL TRIFENATATE (4000013535)	**GLAXOWELLCOME MANUFACTURING PTE LIMITED**, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
LINERIXIBAT (1000020770)	**CHANGZHOU SYNTHEALL PHARMACEUTICAL CO. LTD.**, NO. 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, CN-213127, CHINA	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FLUTICASONE FUROATE (2000014516)

SALMETEROL XINAFOATE (2000008392)

DOLUTEGRAVIR SODIUM (4000014056)

ZIDOVUDINE (1000009208)

FLUTICASONE PROPIONATE (2000008220)

DAPRODUSTAT (3000018715)

CABOTEGRAVIR SODIUM (2000017021)

LAMIVUDINE (1000003255)

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UMECLIDINIUM BROMIDE (4000014045)

ABACAVIR SULFATE (4000003016)

RILPIVIRINE HYDROCHLORIDE (2000016484)

PAZOPANIB (1000011372)

VILANTEROL TRIFENATATE (4000013535)

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