

# 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 43252   |
| 2. Name or corporate name of registrant   | ATNAHS PHARMA UK LIMITED   |
| 3. Permanent or legal address of registrant   | ATNAHS PHARMA UK LIMITED, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place  | ATNAHS PHARMA UK LIMITED, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, 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   | 08/08/2023   |

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

**ATNAHS PHARMA UK LIMITED**, SOVEREIGN HOUSE, MILES GRAY ROAD, BASILDON, SS14 3FR, UNITED KINGDOM

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

#### A Importation

##### Active Substance

FAMCICLOVIR (1000007360)

##### 3rd Country Manufacturer

**HETERO DRUGS LIMITED**, UNIT I, SURVEY NOS 213,2 14 & 255,  
GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, BONTHAPALLY  
VILLAGE, TELANGANA, IN-502 313, INDIA

##### 3rd Country Distributor

|  |   |
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| PROPRANOLOL<br>(1000009764)                | <b>IPCA LABORATORIES LIMITED</b> , P.O. SEJAVTA, RATLAM, MADHYA<br>PRADESH, IN-457001, INDIA  |
| TACROLIMUS (1000002882)                    | <b>BIOCON LIMITED</b> , 20TH KM HOSUR ROAD, ELECTRONICS CITY,<br>BENGALURU, IN-560 100, INDIA   |
| ATENOLOL (1000009849)                      | <b>IPCA LABORATORIES LIMITED</b> , P.O. SEJAVTA, RATLAM, MADHYA<br>PRADESH, IN-457001, INDIA  |
| NAPROXEN (1000009701)                      | <b>INDUSTRIAS QUIMICAS FALCON DE MEXICO, S.A. DE C.V.</b> , KM 4.5<br>CARRETERA FEDERAL CUERNAVACA-CUAUTLA, JIUTEPEC, MORELOS,<br>62578, MEXICO   |
| CALCITRIOL (2000013598)                    | <b>CORDEN PHARMA COLORADO INCORPORATED</b> , 2075 NORTH 55TH<br>STREET, BOULDER, 80301, UNITED STATES   |
| KETOROLAC TROMETAMOL<br>(2000008139)       | <b>MSN LABORATORIES PVT. LIMITED.</b> , SURVEY NOS 317 & 323,<br>RUDRARAM VILLAGE, PATANCHERU MANDAL, SANGAREDDY DISTRICT,<br>TELANGANA, IN-502 329, INDIA  |
| TETRACOSACTIDE<br>HEXAACETATE (2000018735) | <b>BACHEM A.G.</b> , HAUPTSTRASSE 144, BUBENDORF, CH-4416,<br>SWITZERLAND   |
| OLSALAZINE SODIUM<br>(2000008301)          | <b>DOTTIKON EXCLUSIVE SYNTHESIS A.G.</b> , HEMBRUNNSTRASSE 17,<br>DOTTIKON, CH-5605, SWITZERLAND  |
| CHLORTALIDONE<br>(3000004761)              | <b>IPCA LABORATORIES LIMITED</b> , P.O. SEJAVTA, RATLAM, MADHYA<br>PRADESH, IN-457001, INDIA  |
| CLADRIBINE (1000002749)                    | <b>CILAG AG</b> , HOCHSTRASSE 201, SCHAFFHAUSEN, CH-8200,<br>SWITZERLAND  |
| IBANDRONIC ACID<br>(1000003268)            | <b>MAPRIMED S.A. MURGUIONDO</b> , CORONEL PRUDENCIO MURGUIONDO<br>2011, BUENOS AIRES, AR-1440, ARGENTINA<br><b>F. HOFFMANN-LA ROCHE LIMITED.</b> , DEPARTMENT PDR, BUILDING 15,<br>GRENZACHERSTRASSE 124, BASEL, CH-4070, SWITZERLAND |

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|  | <b>WAVELENGTH ENTERPRISES LIMITED.</b> , NEOT-HOVAV ECO-INDUSTRIAL PARK, BEER SHEVA, IL-8413502, ISRAEL   |
| GRANISETRON<br>HYDROCHLORIDE<br>(2000008148) | <b>F. HOFFMANN-LA ROCHE LIMITED.</b> , DEPARTMENT PDR, BUILDING 15, GRENZACHERSTRASSE 124, BASEL, CH-4070, SWITZERLAND                                |
|  | <b>WUHAN BIOCAUSE PHARMACEUTICAL DEVELOPMENT CO., LIMITED.</b> , 4F, 1 BUILDING, HI-TECH INDUSTRIAL PARK, ZHUANKOU, WUHAN, HUBEI, CN-430056, CHINA    |
|  | <b>INDUSTRIAS QUIMICAS FALCON DE MEXICO, S.A. DE C.V.</b> , KM 4.5 CARRETERA FEDERAL CUERNAVACA-CUAUTLA, JIUTEPEC, MORELOS, 62578, MEXICO             |
| NAPROXEN SODIUM<br>(2000008177)              | <b>DIVI'S LABORATORIES LIMITED</b> , UNIT 2, CHIPPADAVILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531 162, INDIA |
| DOXEPIN HYDROCHLORIDE<br>(2000007685)        | <b>TEVA API INDIA PRIVATE LIMITED</b> , PLOT NOS Q1 TO Q4, INDUSTRIAL AREA, GHIRONGI, MALANPUR, BHIND, MADHYA PRADESH, IN-477 117, INDIA              |
| HYDROCORTISONE<br>MICRONISED (3000010308)    | <b>PHARMACIA &amp; UPJOHN COMPANY LLC</b> , 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES  |
| LISINOPRIL DIHYDRATE<br>(2000008500)         | <b>LUPIN LIMITED</b> , UNIT 2, 198-202 NEW INDUSTRIAL AREA NO. 2, MANDIDEEP, DISTRICT RAISEN, MADHYA PRADESH, IN 462046, INDIA                        |

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

|          |   |
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| <b>B</b> | Distribution                            |
|          | CLOBAZAM (1000004171)                   |
|          | FAMCICLOVIR (1000007360)                |
|          | PROPRANOLOL (1000009764)                |
|          | TACROLIMUS (1000002882)                 |
|          | CHLORAL HYDRATE (1000005193)            |
|          | ATENOLOL (1000009849)                   |
|          | NAPROXEN (1000009701)                   |
|          | CALCITRIOL (2000013598)                 |
|          | KETOROLAC TROMETAMOL (2000008139)       |
|          | HYDROCHLOROTHIAZIDE (1000008764)        |
|          | TETRACOSACTIDE HEXAACETATE (2000018735) |
|          | OLSALAZINE SODIUM (2000008301)          |
|          | TRANEXAMIC ACID (1000009308)            |
|          | CHLORTALIDONE (3000004761)              |
|          | CLADRIBINE (1000002749)                 |

CLORAL BETAINE (4000013766)  
IBANDRONIC ACID (1000003268)  
ESTRIOL MICRONISED (2000019289)  
GRANISETRON HYDROCHLORIDE (2000008148)  
NAPROXEN SODIUM (2000008177)  
DOXEPIN HYDROCHLORIDE (2000007685)  
HYDROCORTISONE MICRONISED (3000010308)  
DIAZEPAM (1000003208)  
LISINOPRIL DIHYDRATE (2000008500)

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