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 20782

2. Name or corporate name of registrant ALMAC PHARMA SERVICES LIMITED

ALMAC PHARMA SERVICES LIMITED, ALMAC HOUSE, 20 SEAGOE

3. Permanent or legal address of registrant INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD,

UNITED KINGDOM

4. Address(es) of site(s) where registered activities

take place

ALMAC PHARMA SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, PORTADOWN, CRAIGAVON, NORTHERN IRELAND, BT63 5UA, 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 29/09/2025

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

ALMAC PHARMA SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, PORTADOWN, CRAIGAVON, NORTHERN IRELAND, BT63 5UA, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance 3rd Country Manufacturer

3rd Country Distributor

SODIUM CHLORIDE

(1000009536)

AVANTOR PERFORMANCE MATERIALS, 7001 MARTIN LUTHER KING

BOULEVARD, PARIS, 40361, UNITED STATES

Issue Date: 29 Sep 2025

MACROGOL 3350 THE DOW CHEMICAL COMPANY, ST CHARLES OPERATIONS, (2000012179)LOUISIANA HIGHWAY 3142, HAHNVILLE, 70057, UNITED STATES **MIGALASTAT** CARBOGEN AMCIS AG, HAUPTSTRASSE 171, BUBENDORF, CH-4416, **HYDROCHLORIDE SWITZERLAND** (2000009471)SODIUM HYDROGEN AVANTOR PERFORMANCE MATERIALS, 7001 MARTIN LUTHER KING CARBONATE (3000010012) BOULEVARD, PARIS, 40361, UNITED STATES BIOCON LIMITED, BIOCON SPECIAL ECONOMIC ZONE, PLOT NO. 2, 3 & 4, PHASE IV, BOMMASANDRA-JIGANI LINK ROAD, BOMMASANDRA FIDAXOMICIN (3000016807) POST, BANGALORE, IN-560099, INDIA MIGLUSTAT (1000000278) LONZA AG, LONZASTRASSE, VISP, CH-3930, SWITZERLAND SAPROPTERIN **DOTTIKON EXCLUSIVE SYNTHESIS AG, HEMBRUNNSTRASSE 17** DIHYDROCHLORIDE DOTTIKON, CH-5605, SWITZERLAND (4000008948) F HOFFMANN-LA ROCHE AG, GRENZACHERSTRASSE 124, BASEL, CH-ENTRECTINIB (1000018107) 4070, SWITZERLAND OMADACYCLINE TOSYLATE CARBOGEN AMCIS AG, HAUPTSTRASSE 171, BUBENDORF, CH-4416, (2000019343)**SWITZERLAND** CORDEN PHARMA COLORADO, 2075 NORTH 55TH STREET, BOULDER, 80301, UNITED STATES LINACLOTIDE (1000017589) POLYPEPTIDE LABORATORIES INC., 365 MAPLE AVENUE, TORRANCE,

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FROVATRIPTAN SUCCINATE (2000006383)

90503, UNITED STATES

Issue Date: 29 Sep 2025