

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 32363
2. Name or corporate name of registrant	KOWA PHARMACEUTICAL EUROPE COMPANY LIMITED
3. Permanent or legal address of registrant	KOWA PHARMACEUTICAL EUROPE COMPANY LIMITED, 105 WHARFEDALE ROAD, WINNERSH TRIANGLE, WOKINGHAM, RG41 5RB, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	KOWA PHARMACEUTICAL EUROPE COMPANY LIMITED, 105 WHARFEDALE ROAD, WINNERSH TRIANGLE, WOKINGHAM, RG41 5RB, 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	14/04/2025

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

KOWA PHARMACEUTICAL EUROPE COMPANY LIMITED, 105 WHARFEDALE ROAD, WINNERSH TRIANGLE, WOKINGHAM, RG41 5RB, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
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PITAVASTATIN
CALCIUM
(2000009083)

NISSAN CHEMICAL CORPORATION, 6903-1
OAZA ONODA, SANYO ONODA, YAMAGUCHI,
JP-756-0093, JAPAN

ALGORITHM SAL, SEASIDE ROAD, ZOUK MOSBEH,
BEIRUT, LB 11-962, LEBANON

**RECORDATI ILAC SANAYI VE TICARET ANONIM
SIRKETI**, CERKEKZOY ORGANIZE SAN BOLGESI,
KARAAGAC MAHALLESİ ATATURK CADDESİ,
TEKIRDAG, TR 59500, TURKEY

EZETIMIBE
(1000000757)

ALIVUS LIFE SCIENCES LIMITED, PLOT NO.
3109, G.I.D.C. INDUSTRIAL ESTATE, BHARUCH
DISTRICT, ANKLESHWAR, GUJARAT, IN-
393002, INDIA

ALGORITHM SAL, SEASIDE ROAD, ZOUK MOSBEH,
BEIRUT, LB 11-962, LEBANON