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

UK API 45312 1. Registration Number 2. Name or corporate name of registrant INTERCEPT PHARMA EUROPE LIMITED INTERCEPT PHARMA EUROPE LIMITED, 1 GLASS WHARF, 3. Permanent or legal address of registrant BRISTOL, BS2 0ZX, UNITED KINGDOM INTERCEPT PHARMA EUROPE LIMITED, 1 GLASS WHARF 4. Address(es) of site(s) where registered activities take place BRISTOL, BS2 0ZX, UNITED KINGDOM Regulation 327 of The Human Medicines Regulations 2012 (SI 5. National legal basis of registration 2012/1916) 6. Name of responsible officer of the competent authority of the Confidential member state validating the registration

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

23/01/2024

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

7. Date

Name and address of the site

INTERCEPT PHARMA EUROPE LIMITED, 1 GLASS WHARF, BRISTOL, BS2 0ZX, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance 3rd Country Manufacturer 2rd Country Distributor

Issue Date: 23 Jan 2024

PHARMACIA & UPJOHN COMPANY LLC, 7000 PORTAGE ROAD, KALAMAZOO, 49001-0199, UNITED STATES

OBETICHOLIC ACID (1000018845)

CORDEN PHARMA COLORADO INCORPORATED, 2075 NORTH 55TH STREET, BOULDER, 80301, UNITED STATES

PHARMAZELL SCHWEIZ GMBH, ORISTALSTRASSE 65, LIESTAL, CH-4410, SWITZERLAND



API Registration Number: UK API 45312

Page 2 of 2

Issue Date: 23 Jan 2024