

# 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 33656
2. Name or corporate name of registrant VIFOR PHARMA UK LIMITED
3. Permanent or legal address of registrant VIFOR PHARMA UK LIMITED, THE OLD STABLES, BAGSHOT PARK, BAGSHOT, GU19 5PJ, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place VIFOR PHARMA UK LIMITED - POTTERS DIVISION, 1 BOTANIC COURT, MARTLAND PARK, WIGAN, WN5 0JZ, 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 11/11/2015

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

**VIFOR PHARMA UK LIMITED - POTTERS DIVISION**, 1 BOTANIC COURT, MARTLAND PARK, WIGAN, WN5 0JZ, UNITED KINGDOM

#### 1. MANUFACTURING OPERATIONS

##### Active substance

HOREHOUND EXTRACT  
2000013898

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources |
|   | B.1 Plant Source Extraction                         |
| E | General Finishing Steps                             |

|   |   |
|---|---|
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

VERVAIN EXTRACT

4000013460

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

BURDOCK ROOT DRY EXTRACT

4000013164

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

BLUE FLAG DRY EXTRACT 3:1 CONCENTRATE

4000007054

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

BURDOCK ROOT LIQUID EXTRACT 1:1  
4000013167

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

BONESET LIQUID EXTRACT 1:1  
4000002932

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources |
|   | B.1 Plant Source Extraction                         |
| E | General Finishing Steps                             |
|   | E.1 Physical Processing Steps<br>Drying and Milling |
|   | E.2 Primary Packaging                               |
| F | Quality Control Testing                             |
|   | F.1 Physical / Chemical testing                     |

|  |   |
|--|---|
|  | F.2 Microbiological testing (excluding sterility testing) |
|--|---|

**Active substance**

PASSION FLOWER DRY EXTRACT 5:1

2000005761

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

CLIVERS DRY EXTRACT 4:1

4000013288

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

ELECAMPANE ROOT EXTRACT

4000014124

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources |
|   | B.1 Plant Source Extraction                         |
| E | General Finishing Steps                             |
|   | E.1 Physical Processing Steps<br>Drying and Milling |

|   |   |
|---|---|
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

CLIVERS LIQUID EXTRACT 1:1

4000013290

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

HYSSOP LIQUID EXTRACT 1:1

2000006421

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources       |
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary Packaging                                     |
| F | Quality Control Testing                                   |
|   | F.1 Physical / Chemical testing                           |
|   | F.2 Microbiological testing (excluding sterility testing) |

**Active substance**

ECHINACEA ANGUSTIFOLIA

2000011538

|   |   |
|---|---|
| B | Extraction of Active Substance from Natural Sources |
|---|---|

|   |   |
|---|---|
|   | B.1 Plant Source Extraction                               |
| E | General Finishing Steps                                   |
|   | E.1 Physical Processing Steps<br>Drying and Milling       |
|   | E.2 Primary 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

SLIPPERY ELM BARK  
(4000010549)

**AMERICAN BOTANICALS**, PO BOX 158, 24750 HIGHWAY FF,  
EOLIA, 63344, UNITED STATES

BUTTERNUT BARK POWDER  
(4000013740)

**NATUREX INCORPORATED**, 375 HUYLER STREET, SOUTH  
HACKENSACK, 07606, UNITED STATES

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

### B Distribution

HOPS (3000007607)

SHEPHERDS PURSE (3000008876)

HOREHOUND EXTRACT (2000013898)

SENEGA ROOT (4000010159)

BOLDO DRY EXTRACT (2000006029)

COUCH-GRASS (3000007472)

PRICKLY ASH BARK (2000005765)

CASCARA BARK (4000010238)

BURDOCK ROOT DRY EXTRACT (4000013164)

WILD INDIGO LIQUID EXTRACT 1:1 45% ALCOHOL (4000002664)

HEMLOCK SPRUCE BARK LIQUID EXTRACT 1:1 (4000002243)

SKULLCAP (3000010128)

SENNA PODS POWDERED (4000002377)

JAMAICA DOGWOOD (3000004704)

BURDOCK ROOT LIQUID EXTRACT 1:1 (4000013167)

LOBELIA (3000004265)

ALOES POWDERED (3000016703)

BONESET LIQUID EXTRACT 1:1 (4000002932)

SENNA LEAF (4000010337)

WILD CARROT (3000010502)  
CLIVERS DRY EXTRACT 4:1 (4000013288)  
BUCKTHORN BARK (2000017181)  
DANDELION ROOT POWDER (2000007856)  
ELECAMPANE ROOT EXTRACT (4000014124)  
CLIVERS LIQUID EXTRACT 1:1 (4000013290)  
BAYBERRY BARK LIQUID EXTRACT 1:1 (4000002934)  
HYSSOP LIQUID EXTRACT 1:1 (2000006421)  
ACETUM SCILLAE (4000003385)  
UVA URSI DRY EXTRACT (4000002992)  
IPECAC (3000003474)  
FENNEL SEED POWDER (2000016578)  
ECHINACEA EXTRACT (2000007676)  
PASSIFLORA (1000013999)  
PLEURISY ROOT LIQUID EXTRACT 1:1 35% ALCOHOL (4000002778)  
VALERIAN EXTRACT (2000008486)  
YARROW POWDERED HERB (4000009192)  
ELDER FLOWER HERB, POWDERED (2000016615)