

# 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 18727  |
| 2. Name or corporate name of registrant   | FRESENIUS KABI ONCOLOGY PLC   |
| 3. Permanent or legal address of registrant   | FRESENIUS KABI ONCOLOGY PLC, LION COURT, FARNHAM ROAD, BORDON, GU35 0NF, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place  | FRESENIUS KABI ONCOLOGY PLC, LION COURT, FARNHAM ROAD, BORDON, GU35 0NF, 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   | 19/05/2017  |

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

**FRESENIUS KABI ONCOLOGY PLC**, LION COURT, FARNHAM ROAD, BORDON, GU35 0NF, UNITED KINGDOM

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

#### A Importation

##### Active Substance

GEMCITABINE  
HYDROCHLORIDE  
(2000007951)

##### 3rd Country Manufacturer

**SHILPA MEDICARE LIMITED**, SECOND FLOOR, 10/80 RAJENDRA GUNJ, RAICHUR, IN 584102, INDIA

**FRESENIUS KABI ONCOLOGY, KALYANI**, D-35 INDUSTRIAL AREA, KALYANI, NADIA, WEST BENGAL, IN-741 235, INDIA

##### 3rd Country Distributor

**FRESENIUS KABI ONCOLOGY, KALYANI**, D-35 INDUSTRIAL AREA, KALYANI, NADIA, WEST BENGAL, IN-741 235, INDIA

**SHILPA MEDICARE LIMITED**, SECOND FLOOR, 10/80 RAJENDRA GUNJ, RAICHUR, IN 584102, INDIA

LEVOBUPIVACAINE  
(1000000187)

**FRESENIUS KABI ONCOLOGY, KALYANI, D-**  
35 INDUSTRIAL AREA, KALYANI, NADIA,  
WEST BENGAL, IN-741 235, INDIA

**FRESENIUS KABI ONCOLOGY, KALYANI, D-**  
35 INDUSTRIAL AREA, KALYANI, NADIA,  
WEST BENGAL, IN-741 235, INDIA

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

B            Distribution  
              GEMCITABINE HYDROCHLORIDE (2000007951)  
              LEVOBUPIVACAINE (1000000187)