

# 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 31644                                                                                                          |
| 2. Name or corporate name of registrant                                                                         | CLINIGEN HEALTHCARE LIMITED                                                                                           |
| 3. Permanent or legal address of registrant                                                                     | CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE,<br>FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities<br>take place                                             | CLINIGEN HEALTHCARE LIMITED, UNIT 3, CANADA ROAD, BYFLEET,<br>WEST BYFLEET, KT14 7JL, 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<br>authority of the member state validating the<br>registration | Confidential                                                                                                          |
| 7. Date                                                                                                         | 07/12/2023                                                                                                            |

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

**CLINIGEN HEALTHCARE LIMITED**, UNIT 3, CANADA ROAD, BYFLEET, WEST BYFLEET, KT14 7JL, UNITED KINGDOM

#### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

|   |                                           |
|---|-------------------------------------------|
| B | Distribution                              |
|   | FOSCARNET SODIUM HEXAHYDRATE (2000008388) |
|   | AMIFOSTINE (1000002966)                   |
|   | DEXRAZOXANE HYDROCHLORIDE (2000015254)    |