HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA22937/001/005
Case No: CRN009HLC

The Health Products Regulatory Authority in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Chemi S.p.A.
Via dei Lavoratori, 54, Cinisello Balsamo (MI), 20092, Italy

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Ghemaxan 10,000 IU (100 mg)/1 mL solution for injection in pre-filled syringes

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **19/06/2020** until **18/06/2025**.

Signed on behalf of the Health Products Regulatory Authority this **19th June 2020**

Andrea Kavanagh

Digitally signed by Andrea Kavanagh
DN: cn=Andrea Kavanagh, o=Health Products Regulatory Authority, ou=HPRA, email=andrea.kavanagh@hpra.ie, c=IE
Date: 2020.06.19 14:44:56 +01'00'

A person authorised in that behalf by the said Authority.

General Conditions Applicable to Authorisations

1. The authorisation holder shall ensure that the manufacture, release, supply and advertisement of the medicinal product to which this authorisation relates are in compliance with the Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended, the Medicinal Products (Control of Advertising) Regulations 2007, S.I. No. 541 of 2007, and Council Directive 2001/83/EC as amended and with the details provided in the application except insofar as may otherwise be approved by the Health Products Regulatory Authority.

2. The authorisation holder shall comply with all the conditions attaching to the authorisation, including any special conditions as may be specified in the Schedule to this authorisation.

3. (i) The holder shall immediately inform the Health Products Regulatory Authority of any new information which might affect the risk-benefit balance of the medicinal product and any prohibitions or restrictions placed on the marketing of the medicinal product in another State or jurisdiction.

   (ii) The authorisation holder shall inform the Health Products Regulatory Authority of any material change that has been made or is proposed to be made in the particulars contained in or furnished in connection with the application in relation to the medicinal product to which the authorisation relates.

4. The authorisation holder shall ensure, for the proper surveillance of the medicinal product concerned by this authorisation, that he/she complies with the pharmacovigilance requirements specified in Council Directive 2001/83/EC as amended. The authorisation holder shall have permanently and continuously at his or her disposal an appropriately qualified person for pharmacovigilance. Any change to the qualified person should be notified in writing to the Health Products Regulatory Authority.

5. The authorisation holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of the medicinal product to which the authorisation relates. Such documents shall contain sufficient information to facilitate the withdrawal or recall of a specific batch and each part thereof and shall be kept available for inspection by an authorised officer of the Health Products Regulatory Authority.

6. The authorisation holder shall, if so requested by the Health Products Regulatory Authority, comply with any direction given to it by the Authority to communicate any change to the terms of the authorisation, including the suspension or revocation of this authorisation, to the healthcare professions, the users of the product and, if necessary, the general public.

7. The authorisation holder shall on request by the Health Products Regulatory Authority –
   (i) furnish without payment, from such batch or batches as may be specified, a sample of the product to which the authorisation relates for the purpose of test, examination or analysis,

   or

   (ii) furnish full particulars of the tests which have been applied to such batch or batches of the product as may be specified and the result of such tests.