Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 18442

2. Name of Authorisation Holder PROTHERICS MEDICINES DEVELOPMENT LIMITED

3. Legally registered address of PROTHERICS MEDICINES DEVELOPMENT LIMITED, ST. MARTINS COURT,

Authorisation Holder PATERNOSTER ROW, LONDON, EC4M 7EJ, UNITED KINGDOM

4. Address(es) of Site(s)

PROTHERICS MEDICINES DEVELOPMENT LIMITED, BLAENWAUN, FFOSTRASOL,

LLANDYSUL, SA44 5JT, UNITED KINGDOM

5. Scope of authorisation (complete for

each site under 4)

ANNEX 1

6. Legal basis of authorisation Regulation 18 of the Human Medicines Regulations 2012

7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation

Confidential

8. Date 12/02/2025

Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional)

9. Annexes attached

Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which

authorisation was granted Annex 5 Additional provisions

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

PROTHERICS MEDICINES DEVELOPMENT LIMITED, BLAENWAUN, FFOSTRASOL, LLANDYSUL, SA44 5JT, UNITED KINGDOM

1. MEDICINAL PRODUCTS

- 1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
- 1.2 Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market
- 1.3 Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

Issue Date: 12 Feb 2025

- 2.1 Procurement
- 2.3 Supply
- 2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.3 Immunological medicinal products
- 3.3 Cold chain products (requiring low temperature handling)

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.4 Pharmacy

