Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 36556

2. Name of Authorisation Holder GEDEON RICHTER (UK) LIMITED

3. Legally registered address of GEDEON RICHTER (UK) LIMITED, 127 SHIRLAND ROAD, LONDON, W9 2EP, UNITED

Authorisation Holder KINGDOM

GEDEON RICHTER (UK) LIMITED, 127 SHIRLAND ROAD, LONDON, W9 2EP, UNITED

4. Address(es) of Site(s) 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 Confidential

granting the wholesaling authorisation

8. Date 15/06/2023

Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of

9. Annexes attached contract wholesale distribution sites and their authorisation number Annex 3 (Optional)

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:

GEDEON RICHTER (UK) LIMITED, 127 SHIRLAND ROAD, LONDON, W9 2EP, 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)
- 1.3 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

- 2.1 Procurement
- 2.3 Supply
- 2.4 Export

Issue Date: 15 Jun 2023

- 2.6 Products imported from countries on a list
- 2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

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, 4.2 General Sales List, 4.4 Pharmacy

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