Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 51718

2. Name of Authorisation Holder CLYDESDALE PHARMA LTD

3. Legally registered address of

Authorisation Holder

CLYDESDALE PHARMA LTD, UNIT 3-5 CAMPBELL COURT, BRAMLEY, TADLEY, RG26

5EG, UNITED KINGDOM

CLYDESDALE PHARMA LTD, UNIT 3-5 CAMPBELL COURT, BRAMLEY, TADLEY, RG26

5EG, UNITED KINGDOM

4. Address(es) of Site(s)

CLYDESDALE PHARMA LTD, UNIT 11, CAMPBELL COURT, TADLEY, RG26 5EG, 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

 Name of responsible officer of the competent authority of the member state granting the wholesaling

authorisation

9. Annexes attached

Confidential

8. Date

16/12/2024

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

CLYDESDALE PHARMA LTD, UNIT 3-5 CAMPBELL COURT, BRAMLEY, TADLEY, RG26 5EG, 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

Issue Date: 16 Dec 2024

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.2 Holding
- 2.3 Supply
- 2.4 Export
- 2.6 Products imported from countries on a list
- 2.6a Products certified under Article 51 of Directive 2001/83/EC
- 2.6b Products not 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, 4.5 Traditional Herbal Medicinal products

Name and address of the site:

CLYDESDALE PHARMA LTD, UNIT 11, CAMPBELL COURT, TADLEY, RG26 5EG, 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
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