Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 25258
2. Name of Authorisation Holder	GLENMARK PHARMACEUTICALS EUROPE LIMITED
3. Legally registered address of Authorisation Holder	GLENMARK PHARMACEUTICALS EUROPE LIMITED, BUILDING 2, CROXLEY GREEN BUSINESS PARK, MARLINS MEADOW, WATFORD, WD18 8YA, UNITED KINGDOM
4. Address(es) of Site(s)	GLENMARK PHARMACEUTICALS EUROPE LIMITED , BUILDING 2, CROXLEY GREEN BUSINESS PARK, MARLINS MEADOW, WATFORD, WD18 8YA, 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	09/08/2024
9. Annexes attached	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:

GLENMARK PHARMACEUTICALS EUROPE LIMITED , BUILDING 2, CROXLEY GREEN BUSINESS PARK, MARLINS MEADOW, WATFORD, WD18 8YA, 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)

1.4 With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.6 Products imported from countries on a list

MHRA-GMDP MHRA

2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

3.1.2 Medicinal products derived from blood

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, 4.2 General Sales List, 4.4 Pharmacy

MHRA-GMDP MHRA MHRA-GMDP MHRA