Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 20286

2. Name of Authorisation Holder MERZ PHARMA UK LIMITED

3. Legally registered address of MERZ PHARMA UK LIMITED, GROUND FLOOR SUITE B, BREAKSPEAR PARK,

Authorisation Holder BREAKSPEAR WAY, HEMEL HEMPSTEAD, HP2 4TZ, UNITED KINGDOM

4. Address(es) of Site(s)

MERZ PHARMA UK LIMITED, GROUND FLOOR SUITE B, BREAKSPEAR PARK,

BREAKSPEAR WAY, HEMEL HEMPSTEAD, HP2 4TZ, 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 14/03/2025

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:

MERZ PHARMA UK LIMITED, GROUND FLOOR SUITE B, BREAKSPEAR PARK, BREAKSPEAR WAY, HEMEL HEMPSTEAD, HP2 4TZ, 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

Issue Date: 14 Mar 2025

- 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

Any restrictions or clarifying remarks (for all users)

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

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