Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	UK WDA(H) 36892
2. Name of Authorisation Holder	DUNELM PHARMA LIMITED
3. Legally registered address of Authorisation Holder	DUNELM PHARMA LIMITED, 2 MCMILLAN CLOSE, SALTWELL BUSINESS PARK, GATESHEAD, NE9 5BF, UNITED KINGDOM
4. Address(es) of Site(s)	DUNELM PHARMA LIMITED, 2 MCMILLAN CLOSE, SALTWELL BUSINESS PARK, GATESHEAD, NE9 5BF, 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	29/08/2025
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:

DUNELM PHARMA LIMITED, 2 MCMILLAN CLOSE, SALTWELL BUSINESS PARK, GATESHEAD, NE9 5BF, 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) 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) and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

MHRA-GMDP MHRA

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

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

MHRA-GMDP MHRA-GMDP MHRA-GMDP MHRA-GMDP