Ministerie van Volksgezondheid Welzijn en Sport

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number	:	5139 G
2. Name of Authorisation Holder	:	ACE Pharmaceuticals B.V. (ORG-100000062 / LOC-100005933)
3. Address(es) of Site(s)	:	Schepenveld 41, Zeewolde, 3891 ZK, Nederland Schepenveld 21 12, Zeewolde, 3891 ZK, Nederland
4. Legally registered address of Authorisation Holder	:	Schepenveld 41, Zeewolde, 3891 ZK
5. Scope of authorisation	:	ANNEX 1
6. Legal basis of authorisation	:	Art. 77(1) of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the wholesale distribution authorisation	:	Confidential, Confidential
8. Signature	:	
9. Date	:	2025-12-11
10. 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 (Optional) Additional provisions based on national requirements

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: ACE Pharmaceuticals B.V.
(ORG-100000062 / LOC-100005933)
, Schepenveld 41, Zeewolde, 3891 ZK, Nederland

Human medicinal products

1. MEDICINAL PRODUCTS

1.1. with a Marketing Authorisation or registration in EEA country(s)
1.2. without a Marketing Authorisation or registration in the EEA and intended for EEA market*

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1. Procurement
2.2. Holding
2.3. Supply
2.4. Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1. Narcotic or psychotropic products**
3.2. Products requiring low temperature handling
3.2.1. Temperatures between 2 to 8 °C

Name and address of the site: ACE Pharmaceuticals B.V.
(ORG-100000062 / LOC-100007141)
, Schepenveld 21 12, Zeewolde, 3891 ZK, Nederland

Human medicinal products

1. MEDICINAL PRODUCTS

1.1. with a Marketing Authorisation or registration in EEA country(s)
1.2. without a Marketing Authorisation or registration in the EEA and intended for EEA market*

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1. Procurement
2.2. Holding
2.3. Supply
2.4. Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1. Narcotic or psychotropic products**
3.2. Products requiring low temperature handling
3.2.1. Temperatures between 2 to 8 °C
3.2.2. Other temperatures: (please specify) between -20 to 5 °C tussen -20 en 5 °C

*Art. 5 of Directive 2001/83/EC, Art. 83 of Regulation (EC) 726/2004 and Art. 110 of Regulation 2019/6.
**Without prejudice to further authorisations as may be required according to national legislation.