Ministry of Health, Welfare and Sport - Farmatec | CIBG

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION (MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	:	5139 G
2. Name of Authorisation Holder	:	ACE Pharmaceuticals B.V., ZEEWOLDE
3. Legally registered address of Authorisation Holder	:	Schepenveld 41, ZEEWOLDE, 3891ZK, Netherlands
4. Address(es) of Site(s)	:	Schepenveld 41, ZEEWOLDE, 3891ZK, Netherlands Schepenveld 21-12, ZEEWOLDE, 3891ZK, Netherlands
5. Scope of authorisation (complete for each site under 4)	:	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 wholesaling authorisation	:	Confidential, Confidential
8. Signature	:	
9. Date	:	2021-11-03
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., Schepenveld 41, ZEEWOLDE, 3891ZK, Netherlands

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)
1.2 without a Marketing Authorisation 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 Products according to Art. 83 of 2001/83/EC **
3.1.1 Narcotic or psychotropic products
3.3 Cold chain products(requiring low temperature handling)

Name and address of the site: ACE Pharmaceuticals B.V., Schepenveld 21-12, ZEEWOLDE, 3891ZK, Netherlands

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1.1 with a Marketing Authorisation in EEA country(s)
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3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art. 83 of 2001/83/EC **
3.1.1 Narcotic or psychotropic products
3.3 Cold chain products(requiring low temperature handling)

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004
**Without prejudice to further authorisations as may be required according to national legislation