

**Ministerie van Volksgezondheid, Welzijn en Sport - Farmatec | CIBG -
Cluster Beschikkingen**

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

1. Authorisation Number : 6559 G
2. Name of Authorisation Holder : Orly Pharma B.V., VENLO
3. Legally registered address of Authorisation Holder : Hudsonweg 3, VENLO, 5928LW, Netherlands
4. Address(es) of Site(s) : Hudsonweg 3, VENLO, 5928LW, 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 : 2018-07-05
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: Orly Pharma B.V., Hudsonweg 3, VENLO, 5928LW, 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*
- 1.3 without a Marketing Authorisation in the EEA and intended for exportation

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 **
 - 3.1.2 Medicinal products derived from blood
 - 3.1.3 Immunological medicinal 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