

Ministerie van Volksgezondheid Welzijn en Sport

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number : 109425 G
2. Name of Authorisation Holder : Pharme B.V.
(ORG-100050439 / LOC-100088045)
3. Address(es) of Site(s) : Emmalaan 37, Utrecht, 3581 HP, Netherlands
4. Legally registered address of Authorisation Holder : Emmalaan 37, Utrecht, 3581 HP, 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 : 2024-10-01
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: Pharme B.V.
(ORG-100050439 / LOC-100088045)
, Emmalaan 37, Utrecht, 3581 HP, Netherlands

Human medicinal products

<p>1. MEDICINAL PRODUCTS</p> <p>1.1. with a Marketing Authorisation in EEA country(s) 1.2. without a Marketing Authorisation in the EEA and intended for EEA market</p>
<p>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</p> <p>2.1. Procurement 2.3. Supply</p>
<p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <p>3.1.3. Immunological medicinal products 3.3. Cold chain products(requiring low temperature handling)</p>

*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