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

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number : 5744 G

2. Name of Authorisation Holder : Phardis B.V.

(ORG-100024242 / LOC-100033416)

3. Address(es) of Site(s) : Phoenixstraat 21, Alkmaar, 1812 PP

4. Legally registered address of Authorisation : Phoenixstraat 21, Alkmaar, 1812 PP

Holder

under 4)

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

8. Signature :

9. Date : 2022-11-10

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

: Confidential, Confidential

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: Phardis B.V. (ORG-100024242 / LOC-100033416), Phoenixstraat 21, Alkmaar, 1812 PP

Human medicinal products

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

- 3.1.2. 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