

CIBG

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number : 4545 G
2. Name of Authorisation Holder : Medcor Pharmaceuticals B.V.
(ORG-100013485 / LOC-100019037)
3. Legally registered address of Authorisation Holder : Artemisweg 232, Lelystad, 8239 DE
4. Address(es) of Site(s) : Artemisweg 232, Lelystad, 8239 DE
Schutweg 23, Lelystad, 8243 PC
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 : 2023-11-28
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: Medcor Pharmaceuticals B.V.
(ORG-100013485 / LOC-100019037)
, Artemisweg 232, Lelystad, 8239 DE

Human medicinal products

| |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1. MEDICINAL PRODUCTS</p> <ul style="list-style-type: none">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 |
| <p>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</p> <ul style="list-style-type: none">2.1 Procurement2.2 Holding2.3 Supply2.4 Export |
| <p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <ul style="list-style-type: none">3.1.2 Medicinal products derived from blood3.1.3 Immunological medicinal products3.3 Cold chain products(requiring low temperature handling) |

Name and address of the site: Medcor Pharmaceuticals B.V.
(ORG-100013485 / LOC-100051066)
, Schutweg 23, Lelystad, 8243 PC

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