

Federal Agency For Medicines And Health Products

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number : 1394 H
2. Name of Authorisation Holder : MSF Supply ASBL
3. Legally registered address of Authorisation Holder : Chaussée de Vilvorde 140, Neder-Over-Heembeek (Bruxelles), 1120
4. Address(es) of Site(s) : Chaussée de Vilvorde 140, Neder-Over-Heembeek (Bruxelles), 1120, Belgium
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 : Xavier De Cuyper, +32 2 5284000
8. Signature :
9. Date : 2023-03-17
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: MSF Supply ASBL
, Chaussée de Vilvorde 140, Neder-Over-Heembeek (Bruxelles), 1120, Belgium

Human medicinal products

1. MEDICINAL PRODUCTS

- 1.1 with a Marketing Authorisation in EEA country(s)
- 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

- 3.1.1 Narcotic or psychotropic products
- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.4 Radiopharmaceuticals (including radionuclide kits)
- 3.2 Medicinal gases
- 3.3 Cold chain products(requiring low temperature handling)

Any restrictions or clarifying remarks (for all users): 3.3 Authorized temperatures for the cold chain : 2-8°C and -20°C

3.3 Températures autorisées pour la chaîne du froid : 2-8°C et -20°C

*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