

Bezirksregierung Düsseldorf

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

1. Authorisation Number : DE_NW_03_WDA_2020_0017/ 24.05.05.01-PS
Pharma
2. Name of Authorisation Holder : PS Pharma Service GmbH
3. Legally registered address of Authorisation Holder : Lise-Meitner-Str. 10, Meerbusch, Nordrhein-
Westfalen, 40670, Germany
4. Address(es) of Site(s) : Lise-Meitner-Str. 10, Meerbusch, Nordrhein-
Westfalen, 40670, Germany
Mollsfeld 3, Meerbusch, 40670, Germany
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 : 2020-08-11
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: PS Pharma Service GmbH, Lise-Meitner-Str. 10, Meerbusch, Nordrhein-Westfalen, 40670, Germany

<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 2.2 Holding 2.3 Supply 2.4 Export</p>
<p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <p>3.1 Products according to Art. 83 of 2001/83/EC ** 3.1.1 Narcotic or psychotropic products 3.1.2 Medicinal products derived from blood 3.1.3 Immunological medicinal products 3.3 Cold chain products(requiring low temperature handling)</p>

Any restrictions or clarifying remarks (for all users): To 1.2: cannabis flowers from EU/EWR-states

To 3.1.1: subject to a corresponding authorisation under § 3 BtMG

To 3.3: storage is carried out by the site Mollsfeld 3, 40670 Meerbusch

Zu 1.2: Cannabisblüten aus EU/EWR-Staaten

Zu 3.1.1: vorbehaltlich einer entsprechenden Erlaubnis nach § 3 BtMG

Zu 3.3: Lagerung erfolgt ausschließlich in der Betriebsstätte Mollsfeld 3, 40670 Meerbusch

Name and address of the site: PS Pharma Service GmbH, Mollsfeld 3, Meerbusch, 40670, Germany

<p>1. MEDICINAL PRODUCTS</p> <p>1.1 with a Marketing Authorisation in EEA country(s)</p>
<p>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</p> <p>2.1 Procurement 2.2 Holding 2.3 Supply</p>
<p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <p>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)</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

EudraGMDP