

**Ministry of Social Affairs, Health, Women and Family**

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

1. Authorisation Number : DE\_SL\_01\_WDA\_2019\_0025/5011-018
2. Name of Authorisation Holder : CS-Pharma GmbH
3. Legally registered address of Authorisation Holder : Fabrikstr. 51, Homburg, 66424, Germany
4. Address(es) of Site(s) : Fabrikstr. 51, Homburg, 66424, 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 : 2019-07-02
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:** CS-Pharma GmbH, Fabrikstr. 51, Homburg, 66424, Germany

#### **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**

- 3.3 Cold chain products(requiring low temperature handling)

**Any restrictions or clarifying remarks (for all users):** The company CS-Pharma mainly deals with single imports of medicinal products according to § 73 (3) German Drug Law.

For the field of cytostatic drugs, this permission covers only oral dosage forms  
Die Firma CS-Pharma befasst sich hauptsächlich mit Einzelimporten von Arzneimitteln nach § 73 Absatz 3 AMG.

Für den Bereich Zytostatika umfasst diese Erlaubnis nur orale Darreichungsformen.

\*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