

**Regierungspraesidium Tuebingen, Leitstelle  
Arzneimittelueberwachung Baden-Wuerttemberg**

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

1. Authorisation Number : DE\_BW\_01\_WDA\_2021\_0001\_Takeda\_GmbH
2. Name of Authorisation Holder : Takeda GmbH
3. Legally registered address of Authorisation Holder : Byk-Gulden-Str. 2, Konstanz, Baden-Wuerttemberg, 78467, Germany
4. Address(es) of Site(s) : Byk-Gulden-Str. 2, Konstanz, 78467, 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 : 2021-02-24
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:** Takeda GmbH, Byk-Gulden-Str. 2, Konstanz, 78467, Germany

#### **1. MEDICINAL PRODUCTS**

1.1 with a Marketing Authorisation in EEA country(s)

#### **2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.1 Procurement

2.2 Holding

2.3 Supply

#### **3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

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)

**Any restrictions or clarifying remarks (for all users):** Dispatch and transport of the medicinal products is carried out by the contracted logistics service providers (Trans-o-flex Logistik Service GmbH, Industriegebiet Sued A 12, 63755 Alzenau, Germany and Arvato Supply Chain Solution SE, Gottlieb-Daimler-Str. 1-2, 33428 Harsewinkel, Germany).

Lagerung und Versand der Arzneimittel erfolgt bei den beauftragten Logistik-Dienstleistern (Trans-o-flex Logistik Service GmbH, Industriegebiet Süd A 12, 63755 Alzenau und Arvato Supply Chain Solution SE, Gottlieb-Daimler-Str. 1-2, 33428 Harsewinkel).

\*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