Government of Upper Bavaria - Central Authority for Supervision of Medicinal Products in Bavaria (GMP/GCP)

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

1. Authorisation Number	:	DE_BY_04_WDA_2018/ROB-55Ph-2678.Ph_3-122-17-2
2. Name of Authorisation Holder	:	ilapo Internationale Ludwigs-Arzneimittel GmbH & Co. KG
3. Legally registered address of Authorisation Holder	:	Friedenheimer Brücke 21, München, 80639, Germany
4. Address(es) of Site(s)	:	Friedenheimer Brücke 21, München, 80639, 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	:	2018-03-14
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: ilapo Internationale Ludwigs-Arzneimittel GmbH & Co. KG, Friedenheimer Brücke 21, München, 80639, 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

3.1 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)

*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