

State Office of Health and Social Affairs Berlin

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

1. Authorisation Number : 5373/2-shire/1
2. Name of Authorisation Holder : Shire Deutschland GmbH
3. Legally registered address of Authorisation Holder : Friedrichstraße 149, Berlin, 10117, Germany
4. Address(es) of Site(s) : Friedrichstraße 149, Berlin, 10117, 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 : 2018-02-01
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: Shire Deutschland GmbH, Friedrichstraße 149, Berlin, 10117, Germany

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

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)

*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