

**Freie und Hansestadt Hamburg, Ministry of Health and Consumer
Protection**

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

1. Authorisation Number : DE_HH_01_WDA_517-02.13/01,0275
2. Name of Authorisation Holder : Selectchemie GmbH
3. Legally registered address of Authorisation Holder : Harburger Rathausstraße 37, Hamburg, Hamburg, 21073, Germany
4. Address(es) of Site(s) : Harburger Rathausstraße 37, Hamburg, Hamburg, 21073, 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 : 2019-01-21
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: Selectchemie GmbH, Harburger Rathausstraße 37, Hamburg, Hamburg, 21073, Germany

1. MEDICINAL PRODUCTS

1.2 without a Marketing Authorisation in the EEA and intended for EEA market*

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.3 Supply

2.5 Other activities(s): holding as an outsourced activity in an external warehouse, see annex 5
Lagerung bei einem beauftragten Betrieb, siehe Anlage 5

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.3 Cold chain products(requiring low temperature handling)

Any restrictions or clarifying remarks (for all users): No finished medicinal products according to section 4 subsection 1 Medicinal Products Act (Arzneimittelgesetz) and only transit trade according to section 73 subsection 2 number 3 Medicinal Products Act (Arzneimittelgesetz)
Keine Fertigarzneimittel gem. §4 Abs. 1 Arzneimittelgesetz und nur Transithandel gem. §73 Abs. 2 Nr. 3 Arzneimittelgesetz

*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