

Státní ústav pro kontrolu léčiv

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

1. Authorisation Number : sukls116812/2017
2. Name of Authorisation Holder : COLUSOR s.r.o.
3. Legally registered address of Authorisation Holder : Tuřanka 1222/115, Brno - Slatina, 627 00, Česká republika
4. Address(es) of Site(s) : warehouse is in arex PHARMA s.r.o., K Sokolovně 218, Praha 10 - Uhřiněves, 104 00, Česká republika
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 : 2017-06-05
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: COLUSOR s.r.o., warehouse is in arex PHARMA s.r.o., K Sokolovně 218, Praha 10 - Uhřetěves, 104 00, Česká republika

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
2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art. 83 of 2001/83/EC **
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