State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania

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

1. Authorisation Number

2. Name of Authorisation Holder

3. Legally registered address of Authorisation Holder

4. Address(es) of Site(s)

5. Scope of authorisation (complete for each site under 4)

6. Legal basis of authorisation

7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation

8. Signature

9. Date

10. Annexes attached

: 0822

: UAB "ABC Farma"

: Ryternos g. 5, Kauno r. sav. Karmėlavos sen., Biruliškių k., LT-54469, Lithuania

: Ryternos g. 5, Kauno r. sav., Karmėlavos sen., Biruliškių k., LT-54469, Lithuania

: ANNEX 1

: Art.77(1) of Directive 2001/83/EC

: Confidential, Confidential

.

: 2017-12-18

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: UAB "ABC Farma", Ryternos g. 5, Kauno r. sav., Karmėlavos sen., Biruliškių k., LT-54469, Lithuania

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)
- 3.4 Other products: Biological medicinal products (gene engineering Biologiniai valstiniai preparatai (genų inžinerija)

^{*}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