

Ministerium für Soziales, Gesundheit, Frauen und Familie

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

1. Authorisation Number : DE_SL_01_WDA_2020_002/5011-060
2. Name of Authorisation Holder : 1az Pharm GmbH
3. Legally registered address of Authorisation Holder : Am Nusskopf 35, Schiffweiler, 66578, Deutschland
4. Address(es) of Site(s) : Am Nusskopf 35, Schiffweiler, Saarland, 66578, Deutschland
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 : Stefan Stein, +49 681 5013235
8. Signature :
9. Date : 2021-09-08
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: 1az Pharm GmbH HRB 103602, Am Nusskopf 35, Schiffweiler, Saarland, 66578, Deutschland

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 **
3.1.1 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)

Any restrictions or clarifying remarks (for all users): to 3.1.1: The wholesale license includes narcotics manufactured by Mundipharma, Hexal and Hameln as well as the products Bedrocan, Bediol and Bedrolite from Bedrocan B.V. (obtained from Eucan GmbH).

to 1.1: The wholesale license also includes storage and distribution of ASMOKEN 1.5 mg tablets.
zu 3.1.1: Die Großhandelserlaubnis umfasst Betäubungsmittel der Hersteller Mundipharma, Hexal und Hameln sowie die Produkte Bedrocan, Bediol und Bedrolite der Firma Bedrocan B.V. (bezogen von der Fa. Eucan GmbH).

zu 1.1: Die Großhandelserlaubnis umfasst auch die Lagerung und Distribution für das Präparat ASMOKEN 1,5 mg Tabletten.

*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