

[arms]

**Bezirksregierung Köln**

[regional authority Cologne]

**AUTHORIZATION FOR THE WHOLESALE DISTRIBUTION  
OF MEDICINAL PRODUCTS**

- |   |   |
|---|---|
| 1. Authorization number/file number   | DE_NW_04_WDA_2022-0040-01   |
| 2. Authorization holder   | Acnos Pharma GmbH   |
| 3. Registered address of authorization holder   | Gewerbepark Brand 21<br>52078 Aachen  |
| 4. Address of authorization holder's<br>place of operation  | Gewerbepark Brand 21<br>52078 Aachen  |
| 5. Scope of the authorization<br>(Please indicate for each place of operation<br>listed under 4.)               | Annex 1 (for each place of operation)   |
| 6. Legal basis for authorization  | Sec. 52a (1) German act governing the<br>commerce with medicinal products<br>(Arzneimittelgesetz – AMG) ( <i>German Medicinal<br/>Products Act</i> ) in its current version |
| 7. Name of responsible person at the competent<br>authority of the member state who issues the<br>authorization | Anna Schäferhoff  |
| 8. Signature  | [signature: Anna Schäferhoff]<br>[stamp: regional authority Cologne]  |
| 9. Date   | 27 October 2022   |

10. Annexes

X	Annex 1	Scope of the Authorization
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**Annex 1****SCOPE OF THE AUTHORIZATION**

Name and address of the place of operation:

Acno's Pharma GmbH  
Gewerbepark Brand 21  
52078 Aachen

<b>1.</b>	<b>MEDICINAL PRODUCTS</b>
	<input checked="" type="checkbox"/> Medicinal products for human use <input type="checkbox"/> Medicinal products for veterinary use
<b>1.1</b>	<input checked="" type="checkbox"/> with the authorization to place on the market in a state of the European Economic Area (EEA)
<b>1.2</b>	<input checked="" type="checkbox"/> without the authorization to place on the market in a state of the European Economic Area (EEA) that are placed on the market in the EEA (products not requiring a market authorization) *
<b>1.3</b>	<input checked="" type="checkbox"/> without the permission to place on the market in a state of the European Economic Area (EEA) that are NOT placed on the market in the EEA (medicinal products for third countries)
<b>2.</b>	<b>AUTHORIZED ACTIVITIES</b>
<b>2.1</b>	<input checked="" type="checkbox"/> Procurement
<b>2.2</b>	<input checked="" type="checkbox"/> Storage
<b>2.3</b>	<input checked="" type="checkbox"/> Delivery (supply)
<b>2.4</b>	<input checked="" type="checkbox"/> Export
<b>2.5</b>	<input checked="" type="checkbox"/> Other activities: labeling
<b>3.</b>	<b>MEDICINAL PRODUCTS WITH SPECIAL REQUIREMENTS</b>
<b>3.1</b>	<input checked="" type="checkbox"/> Medicinal products in accordance with Directive 2001/83/EC, Sec. 83 <sup>1</sup> <input type="checkbox"/> Medicinal products in accordance with Directive 2001/82/EC, Sec. 67
<b>3.1.1</b>	<input checked="" type="checkbox"/> Narcotic drugs and psychotropic substances
<b>3.1.2</b>	<input checked="" type="checkbox"/> Medicinal products derived from blood
<b>3.1.3</b>	<input checked="" type="checkbox"/> Immunological medicinal products
<b>3.1.4</b>	<input type="checkbox"/> Radioactive medicinal products (including radionuclide kits)
<b>3.2</b>	<input type="checkbox"/> Medicinal gases
<b>3.3</b>	<input checked="" type="checkbox"/> Medicinal products requiring cold-chain (storage and transportation at low temperatures)
<b>3.4</b>	<input type="checkbox"/> Other activities: (please specify or make reference to Annex 5)

Restrictions or clarifications concerning the scope of the authorization (publicly available)

Re 1.2: cannabis flowers and cannabis extracts only

Re 3.1.1.: subject to a corresponding authorization in accordance with Sec. 3 BtMG (*German Narcotics Law*)

Re 3.3.: incl. frozen medicinal products (-15 °C – 25 °C)

\* Directive 2001/83/EC Sec. 5 or Regulation (EC) 726/2004 Sec. 83

<sup>1</sup> Regardless of further authorizations based on national rules

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For true and complete translation.

Aachen, 14 November 2022

**Karin Feldmann,**

**translator and interpreter for French and English, authorized by the President of the ~~Oberlandesgericht Köln~~  
[Higher Regional Court of Cologne] [AZ 3162-2508 (7)].**

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