

[arms]

Bezirksregierung Köln

[governmental district Cologne]

WHOLESALE DISTRIBUTION AUTHORISATION

- | | |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Authorisation number/file number | DE_NW_04_WDA_2018-0040 |
| 2. Authorisation holder | Acnos Pharma GmbH |
| 3. Registered address of authorisation holder | Kurbrunnenstr. 22
52066 Aachen |
| 4. Address of authorisation holder's
place of operation | Kurbrunnenstr. 22
52066 Aachen |
| 5. Scope of the authorisation
(Please indicate for each place of operation
listed under 4.) | Annex 1 |
| 6. Legal basis for authorisation | Sec. 52a.1 German act governing the commerce
with medicinal products (Arzneimittelgesetz –
AMG) (<i>German Pharmaceuticals Act</i>) in its
current version |
| 7. Name of responsible person at the competent
authority of the member state who issues the
authorisation | Ina Niemann |
| 8. Signature [<i>Signature: Niemann</i>] | [<i>stamp: Bezirksregierung Cologne</i>] |
| 9. Date | 02 May 2018 |

10. Annexes

X	Annex 1	Scope of the Authorisation
---	---------	----------------------------

Annex 1

SCOPE OF THE AUTHORISATION

Name and address of the place of operation:

Acnos Pharma GmbH
 Kurbrunnenstr. 22
 52066 Aachen

1. MEDICINAL PRODUCTS	
<input checked="" type="checkbox"/>	Medicinal products for human use
<input type="checkbox"/>	Medicinal products for veterinary use
1.1	<input checked="" type="checkbox"/> with the authorisation to place on the market in a state of the European Economic Area (EEA)
1.2	<input type="checkbox"/> without the authorisation 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 authorisation) *
1.3	<input 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)*
2. AUTHORISED ACTIVITIES	
2.1	<input checked="" type="checkbox"/> Procurement
2.2	<input checked="" type="checkbox"/> Storage
2.3	<input checked="" type="checkbox"/> Delivery (supply)
2.4	<input checked="" type="checkbox"/> Export
2.5	<input type="checkbox"/> Other activities: (please specify)
3. MEDICINAL PRODUCTS WITH SPECIAL REQUIREMENTS	
3.1	<input checked="" type="checkbox"/> Medicinal products in accordance with Directive 2001/83/EC, Sec. [Art.] 83 ¹
	<input type="checkbox"/> Medicinal products in accordance with Directive 2001/82/EC, Sec. [Art.] 67
3.1.1	<input checked="" type="checkbox"/> Narcotic drugs and psychotropic substances
3.1.2	<input checked="" type="checkbox"/> Medicinal products derived from blood
3.1.3	<input checked="" type="checkbox"/> Immunological medicinal products
3.1.4	<input type="checkbox"/> Radioactive medicinal products (including radionuclide kits)
3.2	<input type="checkbox"/> Medicinal gases
3.3	<input checked="" type="checkbox"/> Medicinal products requiring cold-chain (storage and transportation at low temperatures)
3.4	<input type="checkbox"/> Other activities: (please specify or make reference to Annex 5)

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

NONE

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

[stamp: Bezirksregierung Cologne]

[signature: Niemann]

¹ Regardless of further authorisations based on national rules

For true and complete translation.

The German document was submitted to me as a scan (copy attached).

Aachen, 17 May 2018



Karin Feldmann,
translator for French and English authorised by the President of the Oberlandesgericht Köln
[Higher Regional Court of Cologne] [AZ 3162-2508 (7)].

Von-Pastor-Str. 3 - 52066 Aachen - Germany - Tel.: +49-241 1682197 - feldmann.karin@t-online.de