I hereby certify that the translation overleaf
is a true and correct rendering of the German
document submitted to me.

The German document is attached to this translation.

Bonn, 01.03.2017

Donna Elliott

Dr. Donna Elliott

Sworn translator for English and German
Authorized by the President of the Cologne Higher Regional Court

Register Number: The translation overleaf is entered in my
register under the number 320172019.

Coat of Arms

District Government of Cologne

AUTHORISATION FOR THE WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS

1.	Authorisation number/file number	DE_NW_04_WDA_2017-0002
2.	Name of the authorisation holder	avenar pharma GmbH
3.	Registered address of the authorisation holder	Moltkestraße 25 42799 Leichlingen
4.	Address of the authorisation holder's business premises	Moltkestraße 25 42799 Leichlingen
5.	Scope of authorisation (Please provide information for each of the business premises listed in number 4.)	Appendix 1
6.	Legal basis for the issue of the authorisation	§ 52 a (1) of the Medicinal Products Act (*Arzneimittelgesetz* – AMG) in the version in force from time to time
7.	Name of the responsible case handler of the competent authorities of the Member State issuing the authorisation	Ina Niemann
8.	Signature (Signature) (Stamp of the District Government of Cologne)	
9.	Date	30 January 2017

10. Appendices attached:

☒ Appendix 1 — Scope of the authorisation

APPENDIX 1

SCOPE OF THE AUTHORISATION

Name and address of the business premises:
avenar pharma GmbH
Moltkestraße 25
42799 Leichlingen

1. MEDICINAL PRODUCTS

☒ Medicinal products for human use ☐ Medicinal products for veterinary use

1.1 ☒ with authorisation for placing on the market in a country of the EEA

1.2 ☐ which, without authorisation for placing on the market in a country of the European Economic Area (EEA), are placed on the market in the EEA (exemption from obtaining authorisation)*

1.3 ☐ which, without authorisation for placing on the market in a country of the European Economic Area, are NOT placed on the market in the EEA (medicinal products for third countries)

2. PERMITTED ACTIVITIES

2.1 ☒ Procuring

2.2 ☒ Storing

2.3 ☒ Supplying (delivering)

2.4 ☒ Exporting

2.5 ☐ Other activities: (please describe)

3. MEDICINAL PRODUCTS WITH SPECIAL REQUIREMENTS

3.1 ☐ Medicinal products pursuant to Art. 83 of Directive 2001/83/EC[1]

☐ Medicinal products pursuant to 67 of Directive 2001/82/EC

3.1.1 ☐ Narcotic or psychotropic substances

3.1.2 ☐ Medicinal products derived from blood

3.1.3 ☒ Immunological medicinal products

3.1.4 ☐ Radiopharmaceuticals. (including radionuclides)

3.2 ☐ Medical gases

3.3 ☒ Medicinal products requiring the maintenance of the cold chain (storage and transportation at low temperatures)

3.4 ☐ Other activities: (Please specify or refer to Appendix 5)

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

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*Art. 5 of Directive 2001/83/EC or Art. 83 of Regulation 726/2004/EC

[1]Without prejudice to other authorisations due to national provisions

Source: 151107_F01_01

(Stamp of the District Government of Cologne)

(Signature) Stamp/signature

(Stamp of the District Government of Cologne)