|  |  |
| --- | --- |
| Schlüsselwörter | Großhandel, Erlaubnis, Arzneimittel |
| zugrunde liegendes Qualitätsdokument | VAW 151107 „Entscheidung über die Erteilung einer Großhandelserlaubnis gem. § 52a AMG“ |
| **Querverweise, Bezug** | VAW 151107, Ziffer 3.5.1 |
|  |  |
| **fachlich geprüft** | Dr. Dieter Starke (EFG 09) | 26.04.2022 |
| **formell geprüft** | Dr. Katrin Reder-Christ (ZLG) | 18.05.2022 |
| **CoCP-Vorgabe** | [x]  Ja [ ]  Nein |
| **Pflichtformular** | [x]  Ja [ ]  Nein |
|  | CoCP (EMA/572454/2014 Rev 17):Union Format for a Wholesale Distribution Authorisation (Medicinal Products for Human Use) |
|  |  |
| **im QS-System gültig ab** |  | 23.05.2022 |
| **in Kraft gesetzt** |  |  |

 *(KOPFBOGEN DER ZUSTÄNDIGEN BEHÖRDE)*

“English Translation/Original in German”

## UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

## (MEDICINAL PRODUCTS FOR HUMAN USE AND/OR VETERINARY USE: PLEASE NOTE ANNEX 1)

1. Authorisation number

2. Name of authorisation holder

3. Legally registered address of authorisation holder

4. Address(es) of site(s)

(All sites should be listed, if not covered by separate authorisations)

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

6. Legal basis of authorisation

Sect 52a para 1 des Gesetzes über den Verkehr mit Arzneimitteln -
Arzneimittelgesetz (German Drug Law)

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

8. Signature

9. Date

10. Annexes attached:

 [x]  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:

|  |
| --- |
| 1. MEDICINAL PRODUCTS [ ]  Medicinal Products for Human Use [ ]  Medicinal Products for Veterinary Use**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 **2.5** [ ] Other activities(s): (please specify) |
| 3. Medicinal products with additional requirements**3.1** [ ]  Products according to Art. 83 of 2001/83/EC[[1]](#footnote-1)**3.1.1** [ ]  Narcotic or psychotropic products**3.1.2** [ ]  Medicinal products derived from blood **3.1.3** [ ]  Immunological medicinal products**3.1.4** [ ]  Radiopharmaceuticals (including radionuclide kits)[ ]  Medicinal products for veterinary use**3.1.5** [ ]  Narcotic or psychotropic products**3.1.6** [ ]  Medicinal products for food-producing animals**3.1.7** [ ]  Prescription medicinal products for veterinary use**3.2** [ ] Medicinal gases**3.3** [ ] Cold chain products (requiring low temperature handling)**3.4** [ ]  Other products: (please specify here or make a reference to Annex 5)  |

### Any restrictions or clarifying remarks related to the scope of these wholesaling operations

### \*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004*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 |  dd/mm/yyyy.......................................................... |

*ANNEX 5 (Optional)*

|  |  |
| --- | --- |
| Additional provisions based on national requirements  | ......................................................... |

This translation complies with the original document bearing the signature of the competent authority.

1. Without prejudice to further authorisations as may be required according to national legislation [↑](#footnote-ref-1)