EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENER

Health systems, medical products and innovation
Medical products: quality, safety, innovation

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union format for a wholesale distribution authorisation

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Title	**Union format for a wholesale distribution authorisation**
Date of adoption	1 July 2024
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Notes	Not applicable
Publication date	1 August 2024
Version	1.0

(LETTERHEAD OF COMPETENT AUTHORITY)

Certificate No: _ _ _/_ _ _/_ _ _

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

1. Authorisation number

2. Name of authorisation holder

   2.a Alternative name of authorisation holder (optional)

3. Address(es) of site(s)

   3.a. Additional details on units inspected of site(s) address(es) (optional)

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

4. Legally registered address of authorisation holder

   4.a. Additional details on units inspected of registrant's legal address (optional)

5. Scope of authorisation Annex 1

6. Legal basis of authorisation

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

8. Signature

9. Date

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

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION **ANNEX 1**

Name and address of the site:

☐ **Human Medicinal Products**

☐ **Veterinary Medicinal Products**

1. MEDICINAL PRODUCTS

1.1. ☐ with a Marketing Authorisation or registration in EEA country(s)

1.2. ☐ without a Marketing Authorisation or registration in the EEA and intended for EEA market[1]

1.3. ☐ without a Marketing Authorisation or registration 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 ☐ Narcotic or psychotropic products[2]

3.2 ☐ Products requiring low temperature handling

3.2.1 ☐ Temperatures between 2 to 8 °C

3.2.2 ☐ Other temperatures: (please specify)

3.3 ☐ 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

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[1] Art. 5 of Directive 2001/83/EC, Art. 83 of Regulation (EC) 726/2004 and Art. 110 of Regulation 2019/6.
[2] Without prejudice to further authorisations as may be required according to national legislation.

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	.....