



Union format for a wholesale distribution authorisation

Table of contents:

1. Union format for a wholesale distribution authorisation

Title	Union format for a wholesale distribution authorisation
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Notes	Not applicable
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Version	1.0

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

Name and address of the site:

<input type="checkbox"/> Human Medicinal Products <input type="checkbox"/> Veterinary Medicinal Products

<p>1. MEDICINAL PRODUCTS</p> <p>1.1. <input type="checkbox"/> with a Marketing Authorisation or registration in EEA country(s)</p> <p>1.2. <input type="checkbox"/> without a Marketing Authorisation or registration in the EEA and intended for EEA market¹</p> <p>1.3. <input type="checkbox"/> without a Marketing Authorisation or registration in the EEA and intended for exportation</p>
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<p>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</p> <p>2.1. <input type="checkbox"/> Procurement</p> <p>2.2. <input type="checkbox"/> Holding</p> <p>2.3. <input type="checkbox"/> Supply</p> <p>2.4. <input type="checkbox"/> Export</p> <p>2.5. <input type="checkbox"/> Other activities(s): (please specify)</p>
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<p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <p>3.1 <input type="checkbox"/> Narcotic or psychotropic products²</p> <p>3.2 <input type="checkbox"/> Products requiring low temperature handling</p> <p> 3.2.1 <input type="checkbox"/> Temperatures between 2 to 8 °C</p> <p> 3.2.2 <input type="checkbox"/> Other temperatures: (please specify)</p> <p>3.3 <input type="checkbox"/> Other products: (please specify here or make a reference to Annex 5)</p>

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 dd/mm/yyyy
authorisation was granted

ANNEX 5 (Optional)

Additional provisions based on
national requirements