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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Interpretation of the Union format for a wholesale distribution authorisation

Table of contents

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Interpretation of the Union format for a wholesale distribution authorisation

Union format for a wholesale distribution authorisation

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION	
Human Medicinal Products Veterinary Medicinal Products	If a WDA holder has both human and veterinary medicinal products, Member states may issue a WDA covering both human and veterinary products, or separate WDAs for human and veterinary products.
1. MEDICINAL PRODUCTS	**Examples of use**
1.1. with a Marketing Authorisation or registration in EEA country(s)	WDA holder can perform the authorised operations on any medicinal products for human or veterinary use, which have a marketing authorisation or registration in any country of the European Union and in Iceland, Norway and Liechtenstein (EEA). It is not required that the medicinal product is authorised in the country of the WDA holder if one of the following applies: 1. The product is not going to be distributed to persons authorised or entitled to supply to the public in that country 2. The notification included in Art. 76 of 2001/83/EC is applied 3. The declaration included in Art. 102 of Regulation 2019/6 is applied
1.2. without a Marketing Authorisation or registration in the EEA and intended for EEA market	This paragraph should be ticked when a WDA holder performs the following wholesaling activities: For example 1. Medicinal products for use as referred to in Art. 5 of Directive 2001/83/EC or Art. 83 of Regulation EC/726/2004. 2. Veterinary medicinal products as referred to in Art. 110 of Regulation 2019/6

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION	
	3. Investigational Medicinal Products (IMPs) when a WDA is required by national legislation for the distribution of IMPs.
1.3. without a Marketing Authorisation or registration in the EEA and intended for exportation	1. Medicinal products referred to in Art. 85a of Directive 2001/83/EC, which are directly received from a third country and exported to third countries without being imported into the EEA. 2. Medicinal products manufactured in the EEA, but intended for exportation outside the EEA only.
2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS	**Examples of operations**
2.1. Procurement	Obtaining, acquiring, purchasing or buying medicinal products from manufacturers, importers or other wholesale distributors. Does not include physical handling of medicinal products.
2.2. Holding	Storing medicinal products. Holding means being in physical possession of the medicinal products, without necessarily owning them. Contract warehouses which are actually doing the storing and handling of medicinal products for another WDA holder. A transporter may require a WDA, if they are storing medicinal products for unjustified periods of time during their chosen route of transportation. Custom bonded warehouses: consolidation of freight, storage within free ports (inland container storage sites).
2.3. Supply	All activities of providing / selling / donating medicinal products to wholesalers; pharmacies; or persons authorised or entitled to supply medicinal products to the public. Does not include physical handling of medicinal products.
2.4. Export	All activities relating to the export procedure as defined in the GDP guidelines (i. e. allow Union goods to leave the customs territory of the Union. For the purpose of

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION	
	the guidelines, the supply of medicines from EU Member State to a contracting State of the European Economic Area is not considered as export).
2.5. Other activities(s): (please specify)	Member States may add other activities for which an authorisation is required according to national legislation (e.g. parallel distribution, parallel importation, parallel trade, returned IMPs).
3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS	
3.1. Narcotic or psychotropic products	Additional requirements may be laid down by the member state in respect of wholesale distribution for the following categories of medicinal products. The competent authority may decide not to make available to the public details of these activities.
3.2. Products requiring low temperature handling	
3.2.1. Temperatures between 2 to 8 °C	
3.2.2. Other temperatures: (please specify here)	
3.3. Other products: (please specify here or make a reference to Annex 5)	Member States may use this section to reflect national requirements (e. g. substances that have anabolic, anti-infectious, antiparasitic, anti-inflammatory, hormonal properties and that may be used in animals)
Any restrictions or clarifying remarks related to the scope of these wholesaling operations	All restrictions, such as for a certain category of products only, or certain activities, should be written here. Certain activities can also be limited to only human or veterinary scope.
Optional Annexes	
Annex 2	Only outsourced wholesale distribution operations should be listed here.
Annex 3	Annex 3 is used to list the name of the Responsible Person (s) used by the WDA holder.

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION	
Annex 4	Annex 4 is used to give the date of the inspection on which the WDA was granted.
Annex 5	Annex 5 is used to list any other additional provisions in accordance with national legislation.