# Guideline for Interpreting Annex 1 of the Wholesale Distribution Authorisations granted by Fimea

## Annex 1 (Scope of Wholesale Distribution Authorisation) Contents and Interpretation

### Human and/or Veterinary Medicinal Products

This section defines whether the authorization covers medicinal products intended for humans and/or animals. When necessary, human and veterinary products are listed on separate annexes in the authorisation.

### Name and Site Address of the Authorisation Holder

This section specifies the official name and site location address of the wholesale distributor. If there are multiple sites, each is listed on its own annex. GDP inspection is typically conducted at the address(es) listed here.

### 1. Medicinal Products

1.1. With a Marketing Authorisation or registration in EEA country(s): Covers all products with marketing authorization or registration in Finland.
1.2. Without a Marketing Authorisation or registration in the EEA and intended for EEA market: Includes products requiring special permits and investigational medicinal products to be distributed in Finland or elsewhere in the EEA.
1.3. Without a Marketing Authorisation or registration for Export Outside the EEA: Covers products imported from outside the EEA and exported outside the EEA without being placed on the EEA market, as well as products manufactured in the EEA intended solely for export outside the EEA.

### 2. Authorised Wholesale Distribution Operations

2.1. Procurement: Purchasing from manufacturers, importers, or other wholesalers. Does not include physical handling.
2.2. Holding: Refers to storage or physical possession without necessarily owning the products.

2.3. Supply: Includes all activities related to supplying/selling/donating to wholesalers, pharmacies, or authorized persons. Does not include and require physical handling. For physical handling also 2.2 is required.
2.4. Export: Activities related to export procedures under GDP guidelines. Supplying from an EU member state to another EEA country is not considered export.
2.5. Other Activities (Additional National Requirements):
    2.5.1. Distribution of Medicinal Samples: As defined in Section 35(2) of the Medicines Act.
    2.5.2. Export to Other EEA Countries: Export from Finland to other EEA countries.
    2.5.3. Supply to Customers with Retail Distribution Rights: Required when the wholesaler is responsible for physical delivery to retail distributors (e.g., full-line wholesalers, and direct delivery from foreign manufacturers to pharmacies/hospital pharmacies).
    2.5.4. Receiving and Forwarding Orders: Required if the wholesaler receives orders from retail distributors, but 2.5.3. is not included on the authorisation.
    2.5.5. Other Activities

## 3. Medicinal Products with Additional Requirements

3.1. Narcotic or Psychotropic Products
3.2. Products Requiring Low Temperature Handling:
    3.2.1. Temperatures between 2–8 °C
    3.2.2. Other Temperatures: Specify other low temperatures required (e.g., -40–(-20) °C or below -90–(-60) °C).
3.3. Other Products (Additional National Requirements):
    3.3.1. Medicinal products requiring batch-specific control: Immunological or plasma-derived products (ref: Fimea regulation 4/2019).
    3.3.2. Radioactive Medicinal Products: Products emitting radiation (does not include for example cold kits). These products require special safety measures due to radiation.
    3.3.3. Medicinal Gases: Gaseous products requiring special handling and storage.
    3.3.4. Medicines for Clinical Trials: Includes both investigational and auxiliary products. Note: 1.2 is also required for unauthorized products.
    3.3.5. Homeopathic or Anthroposophic Products: As defined in Section 5b of the Medicines Act.
    3.3.6. Traditional Herbal Medicinal Products: As defined in Section 5a of the Medicines Act.
    3.3.7. Active Substances: Refers to wholesale of medicines not classified as medicinal products (Medicines Act Section 3). In addition, manufacturing, distribution, and import of active substances from outside the EU/EEA requires company registration (refs: Directive 2011/62/EU Art. 52a, Veterinary Regulation 2019/6 Art. 95, Medicines Act Section 11).
    3.3.8. Other: Other products with special requirements not listed above.

## Restrictions or Clarifying Remarks on the Scope of Wholesale Activities:

Any limitations or clarifications related to the scope of wholesale distribution authorisation. Also, certain activities may be restricted to human or animal use only.

If there are discrepancies between language versions, the Finnish version shall be considered the primary basis for interpretation.