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Permits and Documentation

Appendix 5 to the Supply Agreement

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1 Permits

1.1 Distribution

The Supplier is responsible for the distribution of the medicinal product to the hospital pharmacy and is the party that has the physical warehouse from which the medicinal products are sent.

The shipment must be equipped with a validated temperature monitoring device which registers data throughout the transportation period. The data must be available to the hospital pharmacy.

Necessary documentation/equipment to accompany the medicinal product:

- Transport packaging must be marked with the name and address of the responsible importer (Supplier).
- Marking of transport packaging with information about Sender/Exporter.
- Batch Release / CoC documentation for the relevant medicinal product.
- Temperature monitoring equipment for the transportation period that provides temperature data upon receipt of the medicinal product in the pharmacy.

1.1.1 Physical supplier of the medicinal products:

Name:	
Address:	
Country:	
Point of contact:	
Email:	
Telephone:	
Specify applicable permits and refer to EudraGMDP certificate number where applicable:	
Issuer of batch release:	YES/NO (If NO, please also fill in Section 1.1.2)

1.1.2 Issuer of batch release:

Name:	
Address:	
Country:	
Point of contact:	
Email:	
Telephone:	

Specify applicable permits and refer to EudraGMDP certificate number where applicable:	

1.2 Import

1.2.1 The Supplier is responsible for import to Norway.

Approved wholesalers (with a permit from the Norwegian Medicines Agency or the pharmaceutical authority in another EU/EEA country) can import medicinal products from authorised parties in the EU/EEA, provided that it is within the scope of the permit.

Import permit holder:

Name:	
Address:	
Country:	
Point of contact:	
Email:	
Telephone:	
Specify applicable permits and refer to EudraGMDP certificate number where applicable:	

2 Other Documentation

The Supplier shall document having the necessary insurance in Norway, including pharmaceutical insurance and liability insurance.