TECHNICAL TERMS & CONDITIONS

For the purchase and transportation of Intra-EEA Parallel Distributed Medicinal Products between

_____

name, address ('the supplier')

and

axicorp Pharma GmbH, Max-Planck-Str. 36b, 61381 Friedrichsdorf, Germany ('the purchaser')

OBJECT

The object of this agreement is to set out the arrangements and responsibilities between THE SUPPLIER and THE PURCHASER, required by German Medicine Acts and corresponding European Directives, Regulations and Guidelines. Especially concerning current EU Good Distribution Practice (hereinafter referred to as 'GDP') guidance (2013/C343/01), and as set out in Directive 2001/83/EC, as amended, for the purchase, storage and transportation of pharmaceutical products for parallel distribution within the European Economic Area.

EU GDP Guidance (2013/C343/01), Chapter 9 (Transportation) states, in principle, that *'it is the responsibility of the supplying wholesaler to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport'.*

It is, however, a generally accepted principle in the parallel distribution industry that parallel importers purchase goods on an 'ex-factory' or 'ex-works' basis, that is to say, that all responsibility for the condition of the concerned goods passes immediately on purchase to the buyer, and that this modifies the nature of the GDP relationship between supplier and purchaser. This is also the basis on which national competent authorities inspect the operations of parallel importers.

Nevertheless, GDP places differing burdens of responsibility on both parties in these transactions, and this agreement, therefore, addresses the respective responsibilities of the parties in this modified perspective.

RESPONSIBILITIES

a) Of the Supplier

(i) Registration: the supplier confirms his registration with the competent local pharmaceutical authority and his subjectivity to periodical audits.

(ii) WDL: the supplier confirms to provide axicorp Pharma GmbH with a copy of approval notification from the competent local pharmaceutical authority.

(iii) WDL: the supplier confirms to inform axicorp Pharma GmbH immediately in the case of renewal, forfeiture of his wholesale dealer's licence.

(iv) GDP/GMP-Certificate: the supplier confirms to inform axicorp Pharma GmbH immediately in the case of receive, renewal, forfeiture of his GDP/GMP-Certificate, as soon as the certificate is available according to local regulations.

(v) Quality defects: the supplier confirms to submit (using the form attached as appendix 1) all information regarding quality defects of medicines delivered to axicorp Pharma GmbH (Chapter 6), e.g.

a. graduated plans

b. rapid quality notifications

c. complaints and recalls

d. suspected falsified medicinal products

e. notifications of quality alerts by the competent local pharmaceutical authority, by the Marketing Authorisation Holder and any other media distribution channels.

(vi) Quality Management: the supplier confirms that he operates the requisite quality system demanded by GDP (Chapter 1). He further confirms that goods so provided by him to the purchaser have been

placed in free circulation onto the EEA market, and that such sale complies with all relevant local regulations with regard to their export.

(vii) Personnel: the supplier confirms his observance of GDP (Chapter 2), and, in particular, the duties of the Responsible Person.

(viii) Premises and Equipment: the supplier confirms that he maintains suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits, in accordance with GDP (Chapter 3).

(ix) Documentation: the supplier confirms that he maintains an adequate documentation system to record all written procedures, instructions, contracts, records and data, in paper or electronic form, and in accordance with GDP (Chapter 4).

(x) Operations: the supplier confirms that his operations conform to GDP (Chapter 5), with regard to the identity of the medicinal products, in accordance with the information on its outer packaging, that all means available are used to minimize the risk of falsified medicines entering the legal supply chain, and that all products are covered by a marketing authorization granted by the EU or by a Member State.

(xi) Outsourced activities: the supplier confirms that any activity which is outsourced beyond his immediate company should be correctly defined, agreed and controlled under a written contract, in accordance with GDP (Chapter 7).

(xii) Suppliers: the supplier confirms that he will only procure and accept medicinal product from persons authorized to supply medicinal products as wholesalers or holders of a manufacturing or importing authorization granted in accordance with Directive 2001/83/EEC as amended.

(xiii) Self-Inspections: the supplier confirms that self-inspections are from time to time undertaken in order to monitor implementation and compliance with GDP principles (Chapter 8).

(xiv) Packaging for transportation: the supplier confirms to pack and label the goods for transportation according to the latest version of the packaging instruction provided by the purchaser (see appendix 2 or axicorp homepage).

(xv) Transportation: it is acknowledged, as set out in section 1 of this agreement, that all responsibilities regarding the condition of the medicinal products pass to the purchaser after completion of the sale.

(xvi) Transportation: in case the transport is organized by the supplier the supplier confirms to ensure that the transport operation conforms to the GDP guidance. The temperature evaluation of the complete transport operation has to be immediately provided to the purchaser with every delivery.

(xvii) Brokers: the supplier confirms that he will verify that all medicinal products purchased from brokers, as defined in GDP (Chapter 10), have been transacted according the guidance so indicated.

b) Of the Purchaser

(i) Quality Management: the purchaser confirms that he operates the requisite quality system demanded by GDP (Chapter 1).

(ii) Personnel: the purchaser confirms his observance of GDP (Chapter 2), and, in particular, the duties of the Responsible Person.

(iii) Premises and Equipment: the purchaser confirms that he maintains suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits, in accordance with GDP (Chapter 3).

(iv) Documentation: the purchaser confirms that he maintains an adequate documentation system to record all written procedures, instructions, contracts, records and data, in paper or electronic form, and in accordance with GDP (Chapter 4).

(v) Operations: the purchaser confirms that his operations conform to GDP (Chapter 5), with regard to the identity of the medicinal products, in accordance with the information on its outer packaging, that all means available are used to minimize the risk of falsified medicines entering the legal supply chain, and that all products are covered by a marketing authorization granted by the EU or by a Member State.

(vi) Complaints, returns, suspected falsified medicinal products and medicinal product recalls: the purchaser confirms his adherence to the principle and practice of GDP (Chapter 6).

(vii) Outsourced activities: the purchaser confirms that any activity which is outsourced beyond his immediate company should be correctly defined, agreed and controlled under a written contract, in accordance with GDP (Chapter 7).

(viii) Self-Inspections: the purchaser confirms that self-inspections are from time to time undertaken in order to monitor implementation and compliance with GDP principles (Chapter 8).

(ix) Transportation: it is acknowledged as set out in section 1 of this agreement that all responsibilities regarding the condition of the medicinal products pass to the purchaser after completion of the sale. The purchaser confirms that he bears in particular the cost of transportation, and that he ensures that the transport company with which he contracts, or indeed that his own transport operation, conforms to the GDP guidance (Chapter 9).

(x) Packaging for transportation: the purchaser is responsible to hand out the latest version of a packaging instruction to the supplier (see appendix 2 or axicorp homepage).

(xi) Brokers: the purchaser confirms that he will verify that all medicinal products purchased from brokers, as defined in GDP (Chapter 10), have been transacted according the guidance so indicated.

Approval by THE SUPPLIER:

Title, Name, Date and Signature of the Authorized Person

Company Seal

Approval by THE PURCHASER:

Qualified Person

COO Operation, Drug Quality & Safety

Company Seal

Anlage 1/Appendix 1
Information über Qualitätsmängel/Notification of Quality Defects

1	To: axicorp Pharma GmbH Max-Planck-Str. 36b D-61381 Friedrichsdorf			
2	Falls Rückruf vorliegt, Klasse ankreuzen In case of a product recall, circle class of defect	I	II	III
3	Produkt/Product:			
4	Handelsname/Brand name:	INN:		
5	Darreichungsform/Dosage form:	Stärke/Strength:		
6	Chargennummer/Batch number:	Verfallsdatum/Expiry date:		
7	Packungsgröße/Pack size:	Herstelldatum/Date of Manufacture (if available):		
8	Zulassungsinhaber/MA holder:			
9	Hersteller/Manufacturer:			
10	Beschreibung des Qualitätsmangels/Details of Defect:			
11	Von/By (issuing Company):	Kontaktperson/Contact person:		
12	Signatur/Signature:	Datum/Date:	Telefon/Telephone:	