Questionnaire for potential wholesalers / suppliers of medicinal products

(GPDP Guidelines Enclosure 2)

NAME OF THE COMPANY:

……

ARE YOU AN EXISTING EAEPC MEMBER COMPANY? YES/NO

REGISTERED COMPANY ADDRESS:

……

……

……

SHIPPING/DELIVERY ADDRESS FOR GDP ACTIVITIES (if different from above):

……

……

……

NAME OF CONTACT PERSON:

……

POSITION……..

TEL.: ……

FAX: ……

E-Post / Email: ……..

COMPANY ACTIVITIES:

☐ Wholesale with pharmaceuticals with/from
- ☐ Human medicines
- ☐ Veterinary medicines
- ☐ Blood/blood products
- ☐ Nutraceuticals
- ☐ Controlled substances/narcotics
- ☐ Animal vaccines

☐ Import/Export outside EU/EEA (both only export)

☐ Other activities (List) including those that require a manufacturing authorisation:
……
……
……

- ☐ Materials whose handling is subject to special documentation requirements
- ☐ Medical devices
- ☐ Other:
  ……
  ……

1 Introduction

1.1 Brief description of the company:

- Date of initial activity as a wholesaler: ……
- Number of employees: ……
- Number of employees engaged in Quality Assurance: ……

1.2 Date of the last EAEPC or other audit?

……☐ N/A

1.3 Name of auditing company:

……☐ N/A

1.4 Information on suppliers

Pharmaceuticals to be exported are sourced from:

☐ Pharmaceutical manufacturers / MAH, domestically
☐ Pharmaceutical manufacturers / MAH, rest of EU /EEA
☐ Pharmaceutical manufacturers / MAH, third country
☐ Wholesalers domestically
☐ Wholesalers rest of EU / EEA
☐ Other, such as brokers, agents. Please specify:

…….

…….

(NB: Suppliers trading in brokered (3rd party supplied) products require further risk assessment)

1.5 Date of the last official GDP inspection:

……..

1.6 Name of the inspecting authority:

…….

1.7 Forwarding a current wholesale distribution authorisation (WDA)/GDP Certificate: When was the current wholesale distribution authorisation/GDP Certificate issued?

……Please enclose a copy ☐ already sent

Translation of WDA required? YES/NO

Please provide a link to your competent authority's website where your current WDA may be viewed

……

If the above is not possible, please provide a contact name and telephone number of your competent authority for certification purposes

……

(The potential supplier is obliged to notify the purchaser immediately of any changes affecting its WDA, and of any recalls of which it is aware affecting the products supplied)

Do you trade with controlled drugs?

☐ yes ☐ n/a

Do you have the required authorisations?

☐ yes ☐ no ☐ n/a

If "yes": Please enclose a copy of the authorisation / ☐ already seen

Do you trade with blood products?

☐ yes ☐ n/a

Do you have the required authorisations?

☐ yes ☐ no ☐ n/a

If "yes": Please enclose a copy of the authorisation / ☐ already sent

1.8 ISO Certification

☐ yes ☐ no ☐ n/a

If "yes": Please enclose a copy / ☐ already sent

2 Further information

2.1 Please name the responsible person according to GDP, chapter 2.2:

……

3 Notes according to current EU GDP from 5th Nov 2013

Y *YES*
N *NO*
NA *Not applicable*

3.1 Quality assurance

		Y	N	NA	Description
3.1.1	Is a fully documented GDP QMS system implemented according to the type and scope of the activities performed? Does this include CAPAs, Change Controls, Deviations, Risk Assessments (2013 GDP Guide, section 1.2, 1.4)	☐	☐	☐	
3.1.2	Does the management actively review the QMS? Including: CAPAs Change Controls Deviations Risk Assessments (2013 GDP Guide, section 1.2, 1.4)	☐	☐	☐	
3.1.3	Are there clearly defined process descriptions? Are these regularly checked and updated/validated if necessary? (2013 GDP Guide, section 1.2)	☐	☐	☐	
3.1.4	Is it guaranteed in an appropriate manner that	☐	☐	☐	
a)	Pharmaceuticals are only acquired from authorised suppliers including checks on WDA and validity, and a program of risk based audit and due diligence? (2013 GDP Guide, section 5.2)	☐	☐	☐	
b)	The quality is not negatively affected during storage and transport? (2013 GDP Guide, sections 5.5, 9.2)	☐	☐	☐	
c)	Deliveries can be tracked and recalls can be performed (is there a written recall plan)? (2103 GDP Guide, section 6.5)	☐	☐	☐	

d)	The relevant authority and parallel importer/distributor are immediately notified of occurrences or suspicion of falsified pharmaceuticals? (2013 GDP Guide, section 6.4)	☐	☐	☐	
e)	Parallel importer/distributor is immediately notified of occurrences of recalls? (2013 GDP Guide, section 6.5)	☐	☐	☐	
f)	Pharmaceuticals are only delivered to authorised customers? (2013 GDP Guide, section 5.3)	☐	☐	☐	
3.1.5	What is your strategy to prevent the purchase of possible falsified pharmaceuticals? (2013 GDP Guide, sections 5.1 and 6.4) ……				
3.1.6	Is there a fully implemented management of outsourced activities, including: - Assessment of contractors - Contractor Authorisations - Responsibilities between parties - Monitoring of performance - Review of performance - Audit of contractors (2013 GDP Guide, sections 1.3, 7)				

3.2 Personnel

		Y	N	NA	Description
3.2.1	Have rules been set on the responsibilities and competencies of the person(s) responsible, in a verifiable manner? (2013 GDP Guide, section 2.2)	☐	☐	☐	
3.2.2	Is the instruction of new employees guaranteed? (2013 GDP Guide, section 2.4)	☐	☐	☐	
	How? ……				
3.2.3	Do the employees receive instruction on a regular basis? (2013 GDP Guide, section 2.4)	☐	☐	☐	
3.2.4.	How do you authorise the quality assurance staff? (2013 GDP Guide, section 2.3) ……				
3.2.5.	What procedures do you have in place to raise awareness of your staff against possible and suspected falsified medicines? (2013 GDP Guide, section 6.4) ……				

3.3 Facilities, Rooms and equipment, storage

3.3.1	The company has special storage areas for				
	Refrigerated storage (2-8° C)	☐	☐	☐	
	Ambient storage (2-25° C)	☐	☐	☐	
	Freezer storage (0° C)	☐	☐	☐	
	Controlled substances (narcotics – in locked room)	☐	☐	☐	
	Hazardous materials/cytostatics	☐	☐	☐	
3.3.2	Are the premises suitable according to type, state and set-up? (2013 GDP Guide, section 3.1, 3.2) How?.....	☐	☐	☐	
3.3.3	Is the premises protected from access by unauthorised parties? (2013 GDP Guide, section 3.2)	☐	☐	☐	
3.3.4	Are rooms and facilities regularly cleaned, and is the personnel's hygiene of an appropriate level? (2013 GDP Guide, section 2.5, 3.2)	☐	☐	☐	
3.3.5	Is there sufficient protection against pests? (2013 GDP Guide, section 3.2)	☐	☐	☐	
3.3.6	Are environmental factors such as temperature, light, humidity and cleanliness of the premises taken into account? (2013 GDP Guide, section 3.2.1)	☐	☐	☐	

3.3.7	Are appropriate climatic conditions guaranteed in the storage premises: Below 0°C 2-8 °C not above 25°C (e.g. 15-25°C)? (2013 GDP Guide, section 3.2.1)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	
3.3.8	Are climatic conditions in the storage areas subject to: (2013 GDP Guide, section 3.2.1)				
	- temperature mapping?	☐	☐	☐	
	- calibration of equipment?	☐	☐	☐	
	- validation?	☐	☐	☐	
	- monitoring?	☐	☐	☐	
	- recording?	☐	☐	☐	
3.3.9	Is there a functional alarm system installed? (2013 GDP Guide, section 3.3)	☐	☐	☐	
3.3.10	Is a procedure specified for dealing with faults during storage of the pharmaceuticals requiring cold storage, e.g. deviations? (2013 GDP Guide, section 3.3.2)	☐	☐	☐	
3.3.11	Are cold chain products packed at 2-8°C or below 0°C? (2013 GDP Guide, section 9.4)	☐	☐	☐	
3.3.12	Are there separate or secure areas determined for quarantined, falsified, returned pharmaceuticals, or materials for destruction? (2013 GDP Guide, section 3.2, 5.6)	☐	☐	☐	
3.3.13	Are cytostatics, hazardous materials, and materials for destruction adequately stored? (2013 GDP Guide, section 3.2, 5.6)	☐	☐	☐	
3.3.14	Is it ensured that no expired pharmaceuticals are shipped out? (2013 GDP Guide, section 5.7)	☐	☐	☐	

3.4 Sourcing and delivery

		Y	N	NA	Description
3.4.1	Is temperature control assured during a) incoming cold transports with the use of data loggers (2-8°C)? b) other incoming transports (not above 25°C)? (2013 GDP Guide, sections 5.4 and 9.1)	☐ ☐	☐ ☐	☐ ☐	
3.4.2	Is the quality of the pharmaceuticals ensured during transport with the use of data loggers from your source to your warehouse, e.g. cold chain products? (2013 GDP Guide, section 9.1)	☐	☐	☐	

3.4.3	Are the pharmaceuticals protected during transport and protected from the access of unauthorized parties a) during incoming transports? b) from your source to your warehouse? (2013 GDP Guide, section 9.1, 9.3)	☐ ☐	☐ ☐	☐ ☐	
3.4.4	Is product integrity, compatibility with the order and the delivery permit checked when the product is accepted? (2013 GDP Guide, section 5.8)	☐	☐	☐	
3.4.5	Loading for supply: Are cold chain products transferred immediately from below 0°C area or 2-8°C area to freezer or refrigerated truck? (2013 GDP Guide, section 3.3.2)	☐	☐	☐	

3.5 Documentation

3.5.1	Do the documents for the purchase and delivery have the following information? (2013 GDP Guide, section 4.2)				
a)	Delivery date	☐	☐	☐	
b)	Name, quantity and strength of the pharmaceutical	☐	☐	☐	
c)	Name and address of the supplier and recipient	☐	☐	☐	
d)	Batch number and expiry date, where applicable	☐	☐	☐	
3.5.2	Are the required records kept regarding: (2013 GDP Guide, section 2.2)				
a)	Approval by Responsible Person of returns to stock? (2013 GDP Guide, section 2.2 xi)	☐	☐	☐	
b)	Destruction? (2013 GDP Guide, section 2.2 x. 5.6)	☐	☐	☐	
c)	Recalls? (2013 GDP Guide, section 2.2 iv, 6.5)	☐	☐	☐	
d)	Complaints? (2013 GDP Guide, section 6.2)	☐	☐	☐	
3.5.3	Are records kept for at least 5 years?	☐	☐	☐	
3.5.4	Can it be ensured that electronic data records can be safely stored and protected against accidental and unauthorised modifications during the total required storage period and can be made available to read within a reasonable period of time? (2013 GDP Guide, section 3.3.1)	☐	☐	☐	
3.5.5	Are records kept to document that products are in free circulation in the EEA? (See EAEPC GPDP Enclosure 4)	☐	☐	☐	

3.5.6	Is it ensured that supplies to third countries are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with applicable legal and administrative provisions of the country concerned? (2013 GDP Guide, section 5.9)	☐	☐	☐	

3.6 Returned pharmaceuticals

(Does not concern Recalls for which there are separate procedures)

3.6.1	Is a written test instruction available that must be applied to returned pharmaceuticals before they can be re-stored in the warehouse including the following criteria? (2013 GDP Guide, section 6.3)	☐	☐	☐	
a)	Receipt of the purchase from an authorized company	☐	☐	☐	
b)	Explanation of the returning party that the pharmaceuticals can legally be placed on the market, have not left its sphere of responsibility and have been properly stored and handled? (2013 GDP Guide, section 6.3)	☐	☐	☐	
c)	Inspection for integrity and check of original containers (2013 GDP Guide, section 6.3 i)	☐	☐	☐	
d)	Sufficient remaining shelf life (2013 GDP Guide, section 6.3 i)	☐	☐	☐	
e)	Check of marketability (2013 GDP Guide, section 6.3 i)	☐	☐	☐	
f)	Are medicines being returned from a customer not holding a WDA within the recommended 10-day time limit? (2013 GDP Guide, section 6.3 ii)	☐	☐	☐	
g)	Has it been demonstrated by the customer that the returned products have been transported, stored and handled in compliance with their specific storage conditions? (2013 GDP Guide, section 6.3 iii)	☐	☐	☐	
3.6.2	Are the organisational processes recorded in written procedures? (2013 GDP Guide, section 6.3)	☐	☐	☐	
3.6.3	Is the personnel specially trained? (2013 GDP Guide, section 6.3 iv)	☐	☐	☐	

3.7 Self-inspections

3.7.1	Are self-inspections performed regularly? (2013 GDP Guide, section 8.1)	☐	☐	☐	
3.7.2	Are qualified personnel appointed to conduct self-inspections? (2013 GDP Guide, section 8.1)	☐	☐	☐	
3.7.3	Can it be ensured that all relevant areas are checked? (2013 GDP Guide, section 8.2)	☐	☐	☐	
3.7.4	Are records kept on self-inspections and the remedy of deficiencies? (2013 GDP Guide, section 8.2)	☐	☐	☐	
3.7.5	Are the self-inspection documented and implemented under CAPA for continuous improvement? (2013 GDP Guide, section 1.4 ii)	☐	☐	☐	

Date……

……..

Name of responsible person according GDP, in block letters