Guidelines on GDP of Medicinal Products for Human Use

Comments from the Danish Medicines Agency

2.4	We suggest that it should be clarified in the text that: The responsible person should be able to delegate some topics to other competent personnel such as complaints, recalls, approval of returned products to saleable stock etc.
2.7	We suggest to delete "of the distributor" so the line should read: The organizational structure should be defined….
3.4	We question the need for segregation of the medicinal product as the receipt of products applies the same rules regardless whether the endpoint is the Union or outside the Union. At the delivery the endpoint of the product it is not always known and thus it will be a challenge to segregate the product for the distributor.
3.7	As working environment is not a part of GDP we question the need to include this aspect in the guideline.
3.8	Receipt areas and dispatch areas should be separated if possible. We suggest that instead of: … between the receipt and dispatch areas and storage areas…. the text should read: … between the receipt areas and dispatch areas and storage areas…..
3.17	We suggest to include: Alarm systems should be in place as appropriate. We suggest that instead of: Alarm levels should be….. the text should be: Alarm limits should be…. We suggest to include: A system to ensure that the temperature limits has been kept should be established.
4.9	We suggest that instead of: Records must be kept either in the form of purchase/sales invoices, delivery slips, or on computer or in any other form….. the text should be: Records must be kept in the form of delivery slips and consignment notes could also be

	useful. We have several examples of that the recipient does not have the correct specific knowledge of the delivery distributor. The invoice contains information about the money and the delivery slip contains information about the medicinal product. Often the recipient buys the product from the manufacturer while the product is delivered from a wholesaler in between. The recipient thus does not have the wholesale distribution authorization of the distributor but the manufacturing authorization of the manufacturer as they are not aware of the current distribution channel. Basing documentation on only invoices is increasing the risk that the company could receive products from an illegal chain for instance from distributors without wholesale licenses. It is very important that delivery slips and consignment notes are also included in order to give the inspector a better possibility to detect illegal deliveries.
page 15 Principle paragraph 2	The text is "All medicinal products have to have a marketing authorization granted by the EU or by a member state." There is also a distribution of products for compassionate use which do not always have a marketing authorization in the EU. We believe that the guideline should reflect this point.
5.3	The text is: ….must verify that the manufacturer or importer holds a manufacturing authorization. We suggest to add: "- covering the medicinal product in question."
5.4	It should be clarified how many links/generations should be known and documented in the supply chain? Should it be one step back and one step forward?
5.5	We suggest that the qualification of the supplier should be more specified.
6.9 ii)	We suggest that instead of: ….returns from a customer not holding a wholesale distribution authorization…. the text should be: ….returns from a customer not fulfilling this guideline…. Because a pharmacy may not hold an authorization but should in Denmark still fulfill the rules covering GDP.
6.10	We suggest that instead of: ….there is evidence that the product has been stored….

	the text should be: ….there is documentation that the product has been stored…. We suggest that instead of: This evidence should include…. the text should be: This documentation should include….
page 23 Principle	We suggest that instead of: The … contract should cover all wholesale distribution activities… the text should be: The … contract should cover all out sourced wholesale distribution activities…
8.2	We suggest that instead of: Audits by independent external experts…. the text should be: Self-inspections by independent external experts…. We suggest to delete: ... but should not be relied upon as sole means of self-inspection to conform compliance with GDP. In small companies with only few personnel it is a challenge to inspect their own work.
8.4	We suggest that CAPA should be defined in the glossary.
page 26 Principle	We suggest that instead of: It is the responsibility of the wholesale distributor that, during the supply….. the text should be: It is the responsibility of the wholesale distributor that is delivering the medicinal product that, during the supply….
9.8	We suggest that instead of: Dedicated vehicles and equipment should be used, where possible, when handling medicinal products the text should be: Dedicated vehicles and equipment should be used, where appropriate.