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To: SANCO GMP

Subject: Public consultation

Norwegian Medicines Agency has some comments to the GDP guideline, but in total we think this is a good guide and not far away from what we are practicing today.

The first comment counts for the whole document – EU should be changed to EEA countries or EU/EEA and not as to day only EU.

Introduction – second chapter – the line starts with “It is necessary to…… we think ” good manufacturing and distribution practice of medicinal products” should be added.

Chapter 2 Personnel

2.4 is not clear regarding the possibilities to delegate duties – which can be read in point x – it is a mismatch that the RP should carry out his/her activities personally and on the other hand in x delegating his/her duties – only when absent – we think the PR should be allowed to delegate his/her activities always, but only after a written procedure.

Chapter 3 Premises and Equipment

3.4 Medicinal products not intended for the EEA market should be kept in segregated areas or medicinal products intended for export only should be kept in segregated areas.

Chapter 4 Documentation

4.8 Records should be a heading and not a point otherwise text is missing

Chapter 5 Operations

We think the principle is unclear – are we talking about parallel export or parallel import or both?

Chapter 6 Complaints, Returns

6.9 v) a lot of misspelling/errors

6.19 and **6.23** could be said in one point or put together in one point

Chapter 7 Contract Operations

Principle – a new authorisation is introduced - a distribution authorization – should it be “must hold a wholesale distribution authorization”?

Chapter 9 Transportation

It should be stated in the **principle** what sort of authorisation/licence a transport company should hold – then it make sense in point 9.11 to point back to Chapter.

It should be more like the sentence in chapter 10 “Brokers are subject to a registration” - Transporters are subject to a distribution authorization”

If they should have such a licence –who should issues that licence? The Agencies in EEA?

Kind regards

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