

Public consultation of the revised Commission guidelines on Good Distribution Practice of Medicinal Products for Human Use

Reply of the Republic of Hungary

General comments:

Hungary welcomes the draft Commission guidelines on Good Distribution Practice (GDP) of Medicinal Products for Human Use, since it takes duly into account recent amendments of Directive 2001/83/EC while laying down the applicable rules on GDP. It is, however, of utmost importance **to have guidelines on Good Distribution Practice of active substance too.**

Further comments:

Chapter 1 on quality management uses equally the terms *quality system* and *quality management system*. It is not clear, however, whether they have different meanings or they refer to the same notion. If they mean the same, **it is worth considering using the same terminology along the whole text.**

Taking into account the multiple tasks of the responsible person (see point 2.5), which may not be carried out by one person alone, **it could be necessary for the responsible person to have an adequate number of assistance.** This should be represented in the text, alike to point 2.6, where there is a reference to the requirement of having adequate number of human resources ensuring proper task performance.

It is not clear in point 5.24, what kind of system could replace physical segregation. The text mentions – as an example – electronic segregation; however **we would welcome a more detailed specification.**

Regarding Chapter 7 on contract operations, we find it important to lay down in the text that **the written contract on outsourcing should be approved by the responsible person.**

According to Chapter 8 on self-inspections, audits by independent external experts should not be the sole means of self-inspection to confirm compliance with GDP. This restriction is not clear for us, and **we do not understand why audits by independent external experts cannot be the sole means of self-inspections, if these audits cover all aspects of GDP** (and in certain cases might be more objective and independent than a real self-inspection).