

Comments on Guidelines on the principles of good distribution practices for active substances for medicinal products for human use:

In point 25 more clarification is required:

“25. Active substances should be transported in such a way that:

d) they are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, nor to attack by microorganisms or pests.”

- What does it exactly mean “unacceptable degrees of heat, cold” when no special storage conditions are required by the active substance?

In point 27 more clarification is required:

“27. Active substances requiring controlled temperature storage should also be transported by appropriately specialized means.”

- 15-30 °C also means controlled temperature. If there is any excursion, during the transport of an active substance with 15-30 °C storage conditions, can the quality of the product be justified with the results of the accelerated stability data?

Additional item should be added: Date of implementation (*should be precised*)

Explanation: Please take into consideration that this is a huge work to perform. To implement these requirements, QA management of the distributor needs additional resources (staff). To establish a new group for this task within QA and to complete an action plan would take several months.