

Guidelines on Good Distribution Practices

With reference to the **point 9.12** we do not consider appropriate the provision establishing that the storage site at transportation hubs must have the wholesale distribution authorisation when medicinal products are held for longer than 24 hours or for storage of refrigerated products.

In our view a specific authorization granted by the local Health Authorities can guarantee safety requirements and seems to be more appropriate than the proposed one taking into consideration the specific role of transporters compared to the wholesaler's one.

Moreover in the event that medicinal products arrive at the hubs with the approach of the week end or the festivity period we suggest to envisage that the storage period can be prolonged up to 48 hours on exceptionally basis.