Public Consultation on the Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use

Comments from the Czech Republic

General remarks on batch number

The new 2010 legislation strengthens the importance of recording batch numbers during distribution. Despite the fact that under Article 80(e) keeping records on the product´s batch number is mandatory only for medicinal products with safety features we would strongly recommend to apply this requirement to all products on a general basis. We understand that the guideline is not legally binding and cannot go beyond the directive. However, we suggest that (apart from mandatory use) the guideline recommends as a general rule that the batch number is included in all records related to purchase, sale, storage, transport, complaints, and recalls, as well as documents accompanying the medicinal product. Therefore, the words *"where required"* should be deleted from points 4.10 (Documentation), 5.29 (Picking), 5.32 (Delivery) and 10.5. (Specific Provisions for Brokers).

Our experience shows that identification by batch number allows for effective monitoring of the medicinal product´s passage throughout the entire distribution chain up to the persons authorised to supply medicinal products to the public. Traceability of each batch is an essential prerequisite for adopting effective measures in case of serious risk to human life or health, in particular when serious adverse reactions or quality defects are concerned. It allows for easier and better focused exchange of information on quality defects or falsified medicines and for fast and immediate recall of such products from the market.

We believe that in particular for brokered products the batch number must be recorded for all products, not only for those bearing safety features as provided for in Article 80 (e).

It should be noted that the proposed Guideline relies on the batch number where medicinal products are to be returned to saleable stock (see point 6.9. (v): medicinal products which have left the premises of the distributor should only be returned to sealable stock if the distributor has reasonable evidence that the product was supplied to that customer and the batch number of the dispatched product is known.…).

Batch numbers are included also in regular reports on medicinal products supplies which distributors submit to the national competent authority for the purpose of fulfilling its duties and tasks in the area of surveillance over handling medicinal products in all parts of the distribution chain.

Chapter 2 Personnel

Responsible Person

"2.5 - His/her responsibilities include, but are not limited to (x) delegating his/her duties when absent and keeping appropriate records relating to any delegation;"

This point should be amended so as to clarify that under any circumstances the Responsible Person´s responsibilities may be delegated only to another Responsible Person.

Chapter 3 Premises and Equipment

“3.16 Equipment used to control or to monitor the environment of the medicinal product, should be calibrated and their correct operation and suitability for purpose verified at defined intervals by the appropriate methodology.”

We recommend specifying the interval for calibration as stated in Chapter 9 Transportation, i.e. “at regular intervals or at a minimum of once a year” (9.20). Alternatively, the maximum interval of 24 months could be accepted.

Chapter 5 Operations

“5.22 Medicinal products beyond their expiry date or shelf life should be withdrawn immediately from saleable stock either physically or through other equivalent electronic segregation. Physical removal of unsuitable stock should be performed regularly.”

We believe that electronic segregation itself cannot guarantee that expired medicinal products are not dispatched to customers. The only guaranteed way to prevent dispatch of such products is their physical removal from saleable stock.

Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls

According to point 6.9 (ii) medicinal products returned from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within five days of original dispatch.
We do not see any grounds for setting the time limit to five days. The period for return should be indicated in the contract concluded between the distributor and customer. We suggest not to fix any time limit for return back to the distributor. The whole procedure shall be documented and subject to surveillance and approval by the responsible person is necessary.

Transportation

9.5 Delivery drivers (including contract drivers) should be trained in the relevant areas of GDP.

Drivers should be required to document their suitability for handling medicinal

products, e.g. by a criminal record statement.

Temperature control during transport

The intervals for calibration of temperature monitoring equipment during transportation are set to minimum once a year (both for products subject to controlled storage temperature (9.7) and thermolabile products (9.20)). However, there is no specified interval for calibration of the monitoring equipment in storage areas, including areas for storage of medicinal products that need to be stored at low temperatures (3.15 a 3.16). It is appropriate to calibrate such monitoring equipment at the same intervals or at least once in 24 months.

We find it useful to obtain customer confirmation of temperature data demonstrating that the product was kept within defined storage conditions during transport for all products that need to be stored at low temperatures, not only when requested. We consider this as a possibility to prove that the integrity of temperature chain was maintained throughout transportation.

9.12 transportation hubs:" Where medicinal products are held on the premises for longer than this defined time limit, the hub will be ……. required to obtain a wholesale distribution authorisation. For refrigerated product any storage at a transportation hub for any period of time would require that premises to hold a wholesalers distribution authorisation."
It should be clarified who is supposed to hold a wholesale distribution authorisation for such premises. How it should be demonstrated that the time limit of 24 hours before the next stage of transportation route was not exceeded?