Short-term storage of ambient and refrigerated medicinal products – requirements for a Wholesale Dealers Authorisation (WDA)

The EU GDP Guidelines define wholesale distribution as;
“…all activities consisting of procuring, holding, supplying or exporting medicinal products…”

The annexed Glossary of Terms defines holding as “storing medicinal products”.

Medicinal products should therefore only be stored on premises that are covered by a Wholesale Distribution Authorisation.

However, there are certain cases where medicinal products are held for short periods of time during transportation and prior to onward shipment e.g. in the transportation vehicle at motorway service stations or in overnight freight depots.

In such instances it has been determined that, as a matter of policy, a site does not have to be named on a licence where ambient products are stored for less than 36 hours.

**Sites holding ambient products in excess of 36 hours must be licensed.**

This policy applies only where ownership of the products has not been transferred to the person carrying out the storage activities.

Where ownership has been transferred, this is supply and as such the receiving site must be licensed.

It is also important to note that, where wholesaling activities other than storage are being carried out, the site should be named on the relevant licence. This includes the handling of returned goods and where decisions are made regarding suitability for resale, as well as the usual activities of picking against orders.

**Sites where refrigerated products are held, even when this is for less than 36 hours, must be licensed.**

The exception will be where these products are transported and stored overnight in continuously refrigerated vehicles.

**The provisions of Chapter 9.2 of the EU GDP Guidelines must also be observed.**

For further information, contact:
Steve Todd, Senior GDP Inspector
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