

## **Returns of non-defective refrigerated (2c – 8c) medicinal products.**

The requirement for wholesalers to comply with the principles of GDP is stated in European Directive 92/25/EEC Article 10 and Rules and Guidance for Pharmaceutical Distributors 2007.

Guidance for the return of non-defective medicinal products are contained in the Rules and Guidance above, paragraphs 22 – 24, the key element being that;

“products that have left the care of the wholesaler, should only be returned to saleable stock if.....it is known that the goods have been stored and handled under proper conditions” (paragraph 23b) and,

“they have been examined and assessed by a person authorised to do so” (paragraph 23d).

The MHRA re-affirm that the term “proper conditions” can only be interpreted as being under full GDP control by licensed sites. This applies to all categories of medicines.

Medicinal products held in retailers’ unlicensed storage and distribution sites are not considered to be within the licensed distribution network.

The MHRA will adopt a pragmatic approach to the return of non-defective refrigerated medicinal products for those products returned from a customer operating from a **licensed WL site**.

In such circumstances, the return should be completed as expeditiously as possible. The most expedient and appropriate method of transportation must be used.

In every such instance, the Responsible Person or the authorised person receiving the return must be able to demonstrate evidence of “full knowledge” of the storage of the returned products throughout the period it has been with the customer, including transportation.

For those refrigerated medicinal products returned from **unlicensed sites**, the return should be completed within 24 hours including transport.

As above, the Responsible Person or the authorised person must be able to demonstrate evidence of “full knowledge” of the storage whilst at the unlicensed site, including transportation.

**Steve Todd**  
**Senior GDP Inspector**  
**13<sup>th</sup> April 2010**