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July 17, 2014

Mr. David Cockburn
Head of Manufacturing and Quality Compliance
Inspections and Human Medicines Pharmacovigilance
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Dear Mr. Cockburn,

PDA would like to provide some thoughts on the new EU Guideline on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) specifically regarding the requirement for physical and electronic segregation of medicinal products.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. The perspectives here have been prepared by the PDA Pharmaceutical Cold Chain Integrity Group (PCCIG) EU Branch on behalf of our Regulatory and Quality Advisory Board and Board of Directors.

The GDP Guideline currently describes the requirement for medicinal products received from a third country but not intended for the Union market to be physically segregated. Within the pharmaceutical supply chain we have not identified this to be a potential risk to patient safety and in practice these goods are routinely stored in the released stock. These goods are normally identified within the electronic warehouse management system in the same way as returned medicinal products or products pending a disposition decision.

In the next review of the EU GDP guideline we recommend you to make changes to 'Chapter 3/Premises and Equipment/3.2. Premises' by not making any reference to medicinal products received from a third country but not intended for the Union market.

If you have any questions, please contact me.

With very best regards,

Georg Roessling, Ph.D.
Senior VP, PDA Europe
Roessling@pda.org

cc:
Richard Johnson, President, PDA
Rich Levy, Senior Vice President Scientific and Regulatory Affairs, PDA
Erik van Asselt, Chair, PDA PCCIG EU Branch Steering Committee

Attachment

Attachment 1 – EU GDP Guideline referenced paragraph

EU Guidelines of 5 November 2013 on
Good Distribution Practice of Medicinal Products for Human Use
(2013/C 343/01)
CHAPTER 3 — PREMISES AND EQUIPMENT / 3.2. Premises (par. 4)

Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated either physically or through an equivalent electronic system. This includes, for example, any product suspected of falsification and returned products. ~~Medicinal products received from a third country but not intended for the Union market should also be physically segregated~~.

Any falsified medicinal products, expired products, recalled products and rejected products found in the supply chain should be immediately physically segregated and stored in a dedicated area away from all other medicinal products. The appropriate degree of security should be applied in these areas to ensure that such items remain separate from saleable stock. These areas should be clearly identified.