From: MPT - Ian McCorquodale[SMTP:IAN.MCCORQUODALE@CSTPHARMA.CO.UK]
Sent: Wednesday, January 15, 2014 11:08:47 AM
To: ADM-GMDP
Subject: Concerns regarding draft Annex16 of Volume 4 of EU Guidelines for Good Manufacturing Practice
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Dear Sirs,

I have been asked by my employers (MPT Pharma Ltd – a parallel importer / repackager licensed by the MHRA) to contact you with the concerns that MPT Pharma Ltd has regarding the draft Annex 16 to Volume 4 of the "EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use".

Although we view the vast majority of the changes to this Annex as a sensible and realistic progression of the standards, we have doubts and concerns regarding paragraph 3.7.3 :-

"3.7.3 The re-packager should ensure that product intended for repackaging has been obtained from the authorised supply chain and that each sourced batch has undergone certification by a QP prior to its release into the supply chain."

According to the recognised standards of GDP **all such** stock available for sale from the authorised supply chain (i.e. from a licensed wholesaler or direct from the manufacturer) must have undergone QP certification / release prior to being placed on the market by the relevant supplier.

In common with most parallel importers / distributors we purchase our "raw stock" from licensed wholesalers who do not routinely have access to copies of original QP release certificates for the stock that they sell. If we were to request a certificate for stock which the supplier knew was "fraudulent", then surely logic dictates that they would also supply us with a "fraudulent certificate".

We do not see why this requirement is being placed upon stock being purchased for repackaging under parallel importation / parallel distribution without there being a similar constraint applying when the stock is purchased for further distribution without repackaging / parallel distribution. Indeed one could almost consider this a restriction to the free movement of goods compared to the internal market.

We do not understand how this requirement can be viable unless a corresponding requirement is placed upon all players in the supply chain (from manufacturer to final wholesaler) to automatically provide with each batch of product that they supply a copy of the release certificate.

We hope that you will be able to consider our views in your deliberations on this draft document.

Regards,

Ian McCorquodale B.Pharm MRSC

Qualified Person – MPT Pharma

On behalf of MPT Pharma Ltd.