February 2017

New Mailbox for FMD enquiries

As part of our stakeholder engagement work we have set up a dedicated email mailbox to receive enquiries about the implementation of the safety features aspect of the Falsified Medicines Directive. The mailbox is monitored daily and you can expect to receive a response within 5 working days. Please contact us at FMD.safetyfeatures@mhra.gsi.gov.uk

Linear barcodes – can they remain

We have been asked whether the current linear EAN barcodes which are present on most packs can remain or have to be removed under the new requirements. The Delegated Regulation does not make any reference to linear barcodes. You will need to consider whether your customers still require the linear barcodes to manage supply of the medicine within their sector of the supply chain. When you submit your notification to advise us that you will be adding the 2D data matrix code to your pack we will not expect you to remove the linear barcode at that time. It may be that in the future the linear code will become redundant and you will want to remove it. That can be done at any suitable regulatory intervention. The regulatory guidance on how to submit updates to marketing authorisations impacted by the FMD safety features can be found here.

Community pharmacy resources

A website containing information to help community pharmacists prepare for the introduction of the FMD safety features. It has been launched by the UK FMD working group for community pharmacy which includes representatives of the all the main bodies in community pharmacy. This link will take you to the website.

Difference between decommissioning and verification

Verification can take at any time during the movement of the medicine through the supply chain. It is a check of the repository (IT database) that the product is authentic and originates from a legitimate manufacturer. Decommissioning takes places at the end of the supply chain when the product is being supplied to the patient and closes the unique identifier in the repository – so that any other pack bearing the same unique identifier cannot successfully be verified/or decommissioned.

Registering to receive updates

Please help us reach as many stakeholders as possible by forwarding this newsletter to others you think may be interested.

This newsletter will be sent out on a regular basis with helpful information for all stakeholders, and aims to keep you updated on the latest developments with implementation. For further information, visit our webpages, which contain all currently available information.

To register to receive this newsletter directly in future, please email by return with the following:

Your name

Your organisation (if applicable)

Your title (if applicable)

Best regards,

MHRA Safety Features team