



13 March 2018

FMD Safety Features - Newsletter 10

European Commission Q&A

Version 9 of the European Commission Q&A on safety features for medicinal products for human use has been published on their website. This new version includes new questions that will help answer a wider range of queries:

https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v9.pdf

Secondary Care FAQ

In November, NHS Improvement and Specialist Pharmacy Service colleagues published an [FAQ document](#) to help raise awareness and understanding across secondary care. This document will continue to be updated ahead of the implementation deadline of 9 February 2019. Ahead of the next version, if there are further questions which you would like to see included please email them to psc.su@nhs.net or the MHRA's FMD mailbox FMD.safetyfeatures@mhra.gov.uk

SecurMed UK

The European Medicines Verification Organisation (EMVO) announced in guidance to Onboarding Partners (OBP) and future Onboarding Partners in January 2018, that they should consider end of June 2018 as the last opportunity to onboard to EMVO in order to be ready for the FMD go-live. Any onboarding after that date may entail a risk the OBP will not be ready as the onboarding process can take up to 6 months to complete.

With less than 1 year until the FMD go-live, EMVO has issued further information at <https://emvo-medicines.eu/news-events/>

We understand that SecurMed UK is still intending to publish the UK Funding Model by end of Q1 2018, setting out the fee structure and contracting model for Marketing Authorisation Holders. SecurMed UK continues to request all manufacturers and parallel distributors pre-register with SecurMed UK. Please refer to the SecurMed UK website at www.securmed.org.uk for more details on pre-registration information required, the FMD implementation and how to register for the IT System Solution Provider toolkit.

For questions to SecurMed please email info@securmed.org.uk Questions relating to FMD process or compliance should be addressed to FMD.safetyfeatures@mhra.gov.uk

Pack reconciliation

We have recently received queries regarding the requirements placed on manufacturers and wholesalers to fully reconcile stock.

Irrespective of the requirements arising from the delegated regulation MHRA always have and will continue to expect full reconciliation of stock. It is therefore expected that manufacturers will need to reconcile every single pack and decommission any which have been uploaded to the repository and subsequently whilst in their control become damaged or otherwise unfit for supply further down the supply chain. This stems from articles 19 and 22 of the Commission Delegated Regulation [2016/161].

Mailbox

MHRA will continue to answer your questions about FMD through our dedicated mailbox, FMD.safetyfeatures@mhra.gov.uk Please send queries to this mailbox rather than other MHRA email addresses.

The mailbox is monitored daily and we aim to issue a response within 5 working days. If you don't currently receive a copy of the newsletter and would like to, please email by return with the following – your name, your organisation (if applicable) and your title (if applicable).

Best regards,

MHRA Safety Features team