

September 2017

Implementation Advisory Board 07/09/2017

The Safety Features Implementation Advisory Board had a productive meeting on 7th September at MHRA. The Board's remit is to provide advice, support and guidance to DH and MHRA to assist them in ensuring that UK implementation is optimally designed to deliver the full benefits of the FMD whilst minimising the burden throughout the medicines supply chain.

MHRA and DH updated the group on implementation work and news since the last IAB in April 2017 and are planning further bilateral meetings with representatives from the different sectors across the supply chain in Autumn. SecurMed UK updated the group on the appointment of Arvato as the blueprint service provider (BSP) for the UK, on-boarding for the verifications system, communications and upcoming workshops. There was a wide ranging discussion on implementation in each of the different sectors.

SecurMed Workshops

SecurMed are hosting two workshops relating to communications issues surrounding safety features implementation. One will explore ways to grow the verification system and attract a variety of users, while the other will concern the communication strategy for implementation and the extent to which individual organisations will need to take responsibility for this. For more information on these workshops please contact info@securmed.org.uk

UK FMD Working Group for Community Pharmacy

The UK FMD Working Group for Community Pharmacy comprises of expert representatives from NPA, AIMp, CCA, PSNC, CPW, CPS and CPNI. It meets regularly with DH and MHRA to discuss how FMD will operate in UK pharmacies and to seek a practical and pragmatic solution for its implementation. It has recently launched a dedicated website which provides information and guidance on implementation for community pharmacy: https://wkfmdworkinggroup.wordpress.com/ or https://www.fmdsource.co.uk/

<u>Connecting Marketing Authorisation Holders to the European Medicines Verification</u> <u>System</u>

In order to supply most prescription medicines to the European Economic Area after February 2019 all pharmaceutical companies holding marketing authorisations will have to connect to the repositories system (European Medicines Verification System - EMVS) which will enable the pan-European authentication of medicines.

In order to connect to the EMVS, companies have to on-board to the European Medicines Verification Organisation (EMVO), while their Marketing Authorisation Holders (MAHs) within each member state, have to contract with the National Medicines Verification Organisations (NMVO). These two processes are distinct and separate. MHRA is not involved in this process.

You should contact the EMVO for further details of the on-boarding process and the on-boarding fee allocation, through the EMVO Helpdesk at helpdesk@emvo-medicines.eu
For further detail regarding the NMVO Contracting process you will need to contact SecurMed in the UK via info@securmed.org.uk. Contact details for The NMVOs in other countries are available from the EMVO website at the following link: https://emvo-medicines.eu/home/mission/emvs/

Mailbox

MHRA will continue to answer your questions about FMD through our dedicated mailbox, FMD.safetyfeatures@mhra.gov.uk

The mailbox is monitored daily and you can expect to receive 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