August 2017

The Falsified Medicines Directive (FMD) newsletter has now returned!

Over the last couple of months we have been advancing work in critical areas of implementation and continuing to work closely with stakeholders to understand issues. There have been a number of key areas of development:

- SecurMed UK have announced Arvato Systems as the service provide for the UK (more information below).
- Jeremy Hunt and Greg Clark in their joint letter to the Financial Times underlined the UK Government's desire to continue the close working relationship with our European partners on medicines regulation (https://www.ft.com/content/a94326ac-5dbd-11e7-9bc8-8055f264aa8b).
- The Department of Health has met with members of the FMD Community Pharmacy Working Group and will be continuing to work with them to ensure that pharmacies are supported on FMD implementation.
- We are of course to continuing to talk with stakeholders across the supply chain on specific issues.

We will now not be publishing the public consultation until later this year. It is important to note that public consultation will focus only on the small number of flexibilities within the Delegated Regulations (e.g. use of Article 23) and will not explore other broader issues. However, we will be continuing to advance work in other areas in the meantime.

SecurMed UK

In July, SecurMed UK (the UK Medicines Verification System) announced that it was entering into a Letter of Intent with Arvato Systems, the service provider who will implement the IT solution for the UK. The announcement has been published on the ABPI website - http://www.abpi.org.uk/media-centre/Partner-organisation-statements/Pages/SecurMed-UK,-the-UK-Medicines-Verification-Organisation-is-entering-into-a-Letter-of-Intent-with-Arvato-Systems-GmbH-as-the.aspx

IT System Solution Providers in the medicines supply chain have a key role to play in implementing end user systems to comply with the FMD legislation. To commence the FMD implementation activity SecurMed UK and Arvato Systems will be holding half-day workshops in the week of 25-29 September 2017, one focusing on wholesale/distribution solutions and one on dispensing solutions (hospital pharmacy, GPs, community pharmacy and others). There will be approximately 100 places for each workshop and these will be the first engagement sessions with Arvato. The purpose of the workshops will be to walk through the technical requirements for the FMD implementation and for Arvato to give details of the interface specifications, testing & validation procedures, test data, technical documentation and support helpdesk arrangements for IT system solution providers.

Please register your interest to attend or notify your IT provider, indicating whether you serve Wholesalers and/or Dispensers at info@securmed.org.uk. SecurMed UK will notify interested participants in the location and agenda by 20th September 2017.

If you have questions relating to the UK Medicines Verification System, please contact Jerome Bertin, General Manager of SecurMed UK - jerome.bertin@securmed.org.uk - or your industry association (ABPI, BGMA, BAEPD, HDA, CCA, NPA).

On-boarding

If you have any queries about the European Medicines Verification Organisation on-boarding procedure (especially if you are an MAH) please contact them directly - helpdesk@emvo-medicines.eu

Overseas Territories

In light of recent questions – including by the EMVO – around the applicability of the FMD in Gibraltar, we've been in touch with the Government of Gibraltar, via the Foreign Office. They confirmed that it is their legal understanding that the Falsified Medicines Directive does not apply to Gibraltar.

The crown dependencies of the Channel Islands and the Isle of Man will need to meet the requirements of FMD.

Mailbox

The 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