March 2017

Launch of the EMVO on-boarding partner portal

On-boarding of pharmaceutical companies to the European Hub is one of the major tasks being undertaken by the European Medicines Verification Organisation during 2017 and 2018; in total, some 2,500 entities across the EU are expected to register with EMVO for this process over the next two years. In order to expedite this task, EMVO launched an online portal, and offers guidance documents for potential on-boarders. Manufacturers and parallel distributors are encouraged to initiate this process as soon as possible in order to ensure that their systems are compliant in good time for the implementation of the Directive in February 2019.

An EMVO announcements section is now available with further information https://www.emvo-medicines.eu/announcements/. Contact with the EMVO may be made to the Commercial & Partner Management Team (helpdesk@emvo-medicines.eu).

Article 23 Organisations

Within the Commission's delegated regulation there is discretion in some specific areas to consider different implementation options for the UK supply chain. One of the these key areas of flexibility is detailed in Article 23 of the delegated regulation and provides provisions to enable wholesalers to verify and decommission on behalf of groups of organisations who **do not** operate in a healthcare institution or within a pharmacy. These groups of organisations include for example dental practitioners and optometrists, a full list of organisations can be found under Article 23 https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf.

Since the delegated regulation was published in 2016 the FMD project team has been engaging with interested parties to identify a proposed UK solution which keeps costs and burden to a minimum whilst realising the benefits of FMD. As part of this process of engagement for 'safety features' the Government will be launching a public consultation shortly to gather views on how best to implement the regulation. The Article 23 flexibility will be one of key areas of the public consultation where the government has legal scope for change and on which everyone affected can influence the proposed approach to implementation.

Other resources available

The ABPI provide an open website of resources and links on the Falsified Medicines Directive and the Delegated Regulation on 'Safety Features'. This website includes past copies of MHRA newsletter.

http://www.abpi.org.uk/our-work/falsified-medicines-directive/resources-and-links/Pages/default.aspx

Mailbox for FMD enquiries

Please contact us at FMD.safetyfeatures@mhra.gsi.gov.uk

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. 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