18 July 2018

FMD Safety Features - Newsletter 11

Public consultation and impact assessment

MHRA has now published the public consultation on the flexibilities within the Delegated Regulation on Safety Features. The consultation can be viewed and responded to at https://www.gov.uk/government/consultations/implementing-safety-features-under-the-falsified-medicines-directive The consultation will accept responses for a period of 10 weeks ending on 23rd September. We would welcome your responses to the consultation and urge you to disseminate this notice to any interested parties who may not be aware of the publication.

As part of the public consultation, we have published an impact assessment which focuses on the flexibilities of the Delegated Regulation (i.e. the elements where a member state has a choice over implementation). More specifically, this focuses on the flexibilities in Article 23, and the estimated economic costs and benefits of the policy options for implementation of this flexibility. We welcome any feedback on the assumptions and methodology we have used in calculating the economic impacts around this flexibility.

We have also published a draft Statutory Instrument alongside the consultation document. We are consulting on what form of sanctions regime would be the most effective to enforce the regulations across the UK medicines supply chain.

FMD Communications Group

On 10 July the FMD Communications group, sitting under the FMD Implementation Advisory Board, brought together different stakeholders to harmonise and align messages on the implementation of the 'safety features'. It was agreed that each stakeholder group should be responsible for the development of guidance for their own constituency, but the National Competent Authority can provide quality assurance and oversight to help ensure messages are harmonised and comprehensive. A number of actions were agreed and will be taken forward in the coming weeks.

Flexibilities in the Delegated Regulation concerning tamper evident features

Recently we have received feedback that the European Commission's FAQ's on the Delegated Regulation were unclear about whether or not an out of scope medicine (such as a P category medicine) would be allowed to bear tamper evident safety features.

To clarify, this area is within the flexibilities of the Delegated Regulation which will be reflected in our public consultation. Under those flexibilities MHRA is proposing to continue to allow anti-tampering devices to be placed on products that are out of scope on a voluntary basis for the purposes of patient safety. We are not proposing to extend the scope of the unique identifier; a unique identifier should only be applied to medicines that are legally required to comply with the regulation.

Guidance on medicines which are out of scope and packaging

We have attached two documents of interest. One document is a guidance article split into two parts; one half on medicines which are out of scope, and another half on packaging questions. The second document is a list of products which are exempt from the safety features requirements under the provisions of Annex 1 of the Delegated Regulation.

Updated Secondary Care FAQs

In November 2017 (updated again in July 2018), 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. If you have any further questions please email them to psc.su@nhs.net or the MHRA's FMD mailbox FMD.safetyfeatures@mhra.gov.uk

Preventing fraudulent pack notifications for pre-February 2019 packs

We are aware of questions on how to ensure that packs printed legitimately before 9 February 2019 do not trigger a fraudulent pack notification if that pack is dispensed *after* the FMD implementation date. The FAQs published by the European Commission address this issue in Q 1.12 The expectation is that any data encoded prior to the availability of the repositories system should be uploaded retrospectively.

1.12. Question: Would it be possible to place a unique identifier on the packaging of a medicinal product during the 3 years period between the publication of Regulation (EU) No 2016/161 and its application?

Answer: Yes, on a voluntary basis. It is recommended that, whenever possible, unique identifiers are placed on the packaging only once a functional national/supranational repository allowing the storage, verification of the authenticity and decommissioning of those identifiers is in place. Unique identifiers which are placed on medicinal products before such repository is in place are expected to be uploaded in the repository as soon as it becomes operational.

Update from SecurMed UK

MAH Registration and Fee Discount Offers

Following the announcements on the SecurMed UK MAH Fee Model in April/May 2018 we are encouraging all Marketing Authorisation Holders and Parallel Distributors who have not registered with SecurMed UK to do so. The first discounted MAH Setup Fee offer has now ended and all new registrees will be assigned to the second discount offer; for which registrations close on Friday 14-Sep-2018 and all fee payments for this offer must be received by Monday 30-Sep-2018 at 17.00 BST (18.00 CET). You can download Registration Forms from our website at www.securmed.org.uk and they should be submitted by email to mah@securmed.org.uk .

Micro MAH Fee Waiver Offer

On 01-Jun-2018 SecurMed UK announced a micro MAH fee waiver offer for small companies. All MAHs who apply for the fee waiver offer must complete a Registration Form and sign an MAH Agreement and submit them to mah@securmed.org.uk . The MAH fee waiver offer is assessed against the MAH legal entity (the company) not individual marketing

authorisations. All UK and non-UK companies are assessed in the same manner. You can find more details on how to apply at our website at www.securmed.org.uk .

UK Medicines Verification System Status

SecurMed UK has been working closely with our supplier Arvato Systems to prepare the UK Medicines Verification System for deployment. We are intending to deploy our IQE Test Environment connected to EMVS in late July/ early August and the Production environment in early September. For each deployment we will be performing a controlled startup; we will be seeking a small group of manufacturers/MAHs, IT providers and end users to work with initially support these activities. SecurMed will be engaging with the Community Pharmacy, Wholesaler and Manufacturer/MAH FMD working groups to identify suitable participants in this group.

End user registration and onboarding processes are in development and we expect to launch those in September/October.

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

NHS Digital

NHS Digital are working alongside MHRA & DHSC to support system suppliers with developing FMD functionality in their systems. System suppliers, or organisations wishing to seek technical or process advice, can contact the NHS Digital team at FMD@nhs.net

Policy queries should still be sent to the MHRA FMD inbox.

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).

Our privacy policy

At the Medicines and Healthcare products Regulatory Agency, we have recently published our new privacy policy in line with the new requirements of the General Data Protection Regulation. You can view this at the following link:
https://www.gov.uk/government/publications/mhra-privacy-notice

We retain your email address so that you and other stakeholders impacted by FMD can continue to receive the newsletter. If you wish to continue receiving the newsletter, no action is required. If you would like to unsubscribe from our mailing list, please reply with 'Unsubscribe' in the subject line.

Best regards,

MHRA Safety Features team