FMD Safety Features – Newsletter 13

The countdown is on…..One more day to go until 9 February implementation date

Over the last few months there has been a lot of work happening across all sectors to get ready for the fast approaching 9 February implementation date. Additional guidance documents have been added to our central FMD information hub, the Government response to the public consultation was published and much more…….

New guidance released on 7 February 2019

Yesterday we released a final statement ahead of Go Live - here

The main article was as follows:

The United Kingdom is committed to meeting the 9 Feb 2019 deadline for the launch of EU FMD safety features Delegated Regulation, and we expect all stakeholders in the UK supply chain to be aiming to comply with these new requirements, indeed we know much of the UK supply chain is already prepared.

Despite the significant work undertaken to date in the UK and given the complexities associated with setting up the medicines verification system across the EU it is anticipated issues will arise especially during the initial operational/implementation phase. It is important that these issues do not compromise confidence in the medicines supply chain. The Government's priority is the continued supply of safe medicines to patients.

For example, several Member States have formally advised those who may receive 'unknown' error messages to dispense anyway. Therefore, the MHRA will also be taking a pragmatic, flexible approach to how we enforce the new legal requirements, as long as the normal checks are carried out, and there is no reason to think that the medicine is falsified. This position will be kept under review.

We are also aware of issues around non-FMD compliant packs released to market before 9 February 2019, and wholesalers' designated status. We will continue to work with UK stakeholders to help bring them into full compliance with the safety features regulation as soon as possible.

More information on error messaging and false alerts

Medicinal products manufactured and released before 9 February 2019 containing safety features may not necessarily be fully uploaded to the repositories system. There are also

packs of medicines already on the UK market which contain 2D barcodes that do not relate to the FMD safety features due to other international initiatives. Attempts to verify or verify and decommission these products will trigger system alerts. This situation may continue for a period of time due to the shelf life of medicinal products, in some cases up to five years. Where Alert IDs are triggered please refer to the guidance published by the Royal Pharmaceutical Society, and the UK FMD working group.

Any instances of suspected falsification (including physical signs of tampering) are to be reported in the usual way via the yellow card scheme using the 'Fake' button.
Where the Marketing Authorisation Holder is notified by the alerting system that a data error has occurred, they are to notify the MHRA if upon further investigation, falsification is suspected.

FMD guidance page - Gov.uk

As a reminder, the FMD guidance page on gov.uk is the place to access all information relating to FMD Safety Features. With both UK Government and stakeholder produced information; those impacted by the new Regulation can access the most up to date advice on how to prepare for the implementation of and compliance with the Safety Features Regulation.
Through the guidance pages, in addition to the guidance for all, stakeholders can scroll down the pages to access sector-specific guidance based on their self-classification e.g. there is a section for wholesalers with links to Government and externally produced guidance.
By hosting UK Government advice and links to 3rd party stakeholder organisations that are experts in sector specific fields or FMD implementation, the gov.uk pages on FMD are a one stop shop for information and are intended to be the first port of call for anyone wishing to know more.

Updated guidance documents

Over the last few weeks there have been several guidance documents published on or linked to via Gov.uk, including the following;

- Guidance for Wholesalers
- Guidance for parallel import license holders
- Homecare
- Additional guidance on Article 23 providers, Healthcare Institutions and Article 26 exemption
- RPS professional guidance for pharmacists

FMD Mailbox and MHRA Q&A guidance document

Any questions about FMD and the Safety Features not covered by published guidance can be directed to fmd.safetyfeatures@mhra.gov.uk. We apologise to anyone who has not received a prompt response to their enquiry – rather than reply to all of them individually we have compiled the key themes into a Q&A document covering all queries relevant to the National Competent Authorities, which we will update and share with additional topics, and should be read alongside more specific guidance produced by other stakeholders.

Any questions about FMD and the Safety Features not covered by published guidance can be directed to fmd.safetyfeatures@mhra.gov.uk.

General Pharmaceutical Council (GPhC) and MHRA ways of working

MHRA and GPhC have been working closely together to make sure the new FMD requirements are met and medicines are safe for public use. A joint statement has been released on the GPhC website here to explain the roles of the regulators.

NHS Digital – Toolkits

NHS Digital was commissioned to develop sector specific guidance toolkits for healthcare providers to help them prepare for FMD. These include the following:

- Secondary Care
- Community Pharmacy
- Dispensing Doctors
- GP Surgery

These toolkits can be accessed here or via the FMD guidance hub

Guidance - What a good product / bad product looks like (Jonathan Buisson)

The UK FMD Working group for Community Pharmacy has produced some guidance which should help end users to identify the types of packs that will need scanning for verification and authentication, and the features they should look out for and those that will not need authentication.

Guidance and examples of “right” and “wrong” packs can be found here

Public consultation on No deal Brexit – Government Response

Following our consultation on how medicines, medical devices and clinical trials would be regulated in a no-deal scenario, the Medicines and Healthcare products Regulatory Agency has today issued updated guidance setting out the UK’s proposed arrangements for regulation if we leave the EU on 29 March 2019 with no deal.

The relevant section on FMD is as follows:

The UK is proceeding with implementation of the EU requirements for new safety features to prevent the entry into the legal supply chain of falsified medicinal products in the UK. However, as stated in the MHRA’s consultation, in the event of no deal, it is expected UK stakeholders would no longer be able to comply with the requirement to verify and authenticate. Therefore, the legal obligations related to this would be removed for all actors in the UK supply chain.

Packs containing the Falsified Medicines Directive (FMD) safety features would still be accepted in the UK, provided that they are in line with other UK packaging requirements. In the interests of public safety, we will evaluate the options for a future UK falsified medicines regulatory framework, taking into account the investment already made by stakeholders.

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.

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