7 February 2019

Dear Colleague,

FMD Advice Notice

The 'Safety Features' Delegated Regulation, part of the EU Falsified Medicines Directive (FMD), will apply in the UK from 9 February 2019. The Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health & Social Care (DHSC) continue to work with stakeholders across the supply chain to support implementation to the right standard and on time. The Government does not underestimate the challenge and complexity of implementing the new FMD requirements in the NHS, not least the tight time-frame stakeholders have been working to.

The MHRA, which is responsible for the overall enforcement of the new FMD requirements, has been clear that its priority is to seek compliance, working pragmatically with stakeholders to ensure that implementation does not prevent medicines from reaching the patients that need them. Our number one priority is the safety of the public, and more information will follow on how these new checks will be incorporated into the Care Quality Commission's inspection regime.

In preparing for all eventualities the MHRA (who DHSC are jointly working with) have now published their consultation response, which is clear that in an event of a No Deal we would have to remove the FMD requirements from law as we would no longer have access to the EU system. Whilst we remained mandated to continue preparations these need to continue with appropriate caution given the possibility of a No Deal scenario.

FMD is a stakeholder led model. DHSC/MHRA have been working with colleagues in the NHS to support implementation across the different sectors including for hospital and community pharmacies and General Practitioners including Dispensing Doctors. NHS Digital are progressing work on toolkits for each of these sectors which are published as soon as they become available. Work has also been progressing with system suppliers to provide an FMD solution as part of their package.

Healthcare institutions are required to 'verify and decommission' medicines supplied or administered directly to patients. ALL GP Practices 'personally administer' some medications (namely Vaccines/Immunisations) and the decommissioning of these elements are covered via the GPIT Operating Model arrangements and centrally funded. Dispensing doctors and community pharmacies would need to make their own provision for verification and decommissioning as part of dispensing.

Further information is available at Gov.uk: https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features to support you in complying with the new requirements.

Yours sincerely

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