

## **Position Statement: Falsified Medicines Directive 18 January 2019**

The Falsified Medicines Directive is an EU initiative which will be implemented from 9th February 2019. The government have committed to introducing the directive. It is being introduced to improve the safety of medicines and address concerns about counterfeit drugs being circulated in the European market. It will mean that medication packs produced after 9th February 2019 will have a unique identifier shown as a barcode, be tamper resistant and will be logged into a central database. The medicines can be verified as they move through the supply chain and every medicine will be logged out (decommissioned) when it is issued to a patient or destroyed. A scanner to identify the barcode and link to the database is an essential requirement. GP surgeries are defined as healthcare institutions under the EU directive, so this will affect all practices. The impact will be most significant on pharmacies and dispensing doctors.

The minimum that every practice will need is a scanner to read the barcodes so that they can decommission the medicine. For non-dispensing practices, this is likely to affect vaccines and personally administered items. For dispensing doctors, this will add an extra step to the dispensing of every drug pack. The BMA and Dispensing Doctors Association are aware that this will generate additional work in the dispensing process and will require the updating of practices standard operating procedures and training for staff. The BMA's position on IT is that the NHS should bear any IT cost associated with the FMD and this includes scanners.

Although the implementation date is looming, our advice is not to panic and to await clear national guidance. It is likely there will be a phased implementation as the appropriate infrastructure needs to be in place. In the event of the UK leaving the EU without a deal in place, the UK will not have access to the European central data hub. In this case it is unlikely the directive will be implemented in its current form.

Please click link to the BMA website for further information here.

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The information provided in this document is correct at the time of publication. Please see the Derby and Derbyshire LMC website for any revisions.







