NPA brief guide to the **EU Falsified Medicines Directive**

The EU Falsified Medicines Directive (FMD), which has been introduced to reduce the risk of counterfeit medicines in the supply chain, comes into force on 9th February 2019. From this date, all prescription medicine packs must have a unique code which will be placed on the packaging in the form of a 2D barcode (data matrix). The unique code will be held in a national database. There will be a requirement for pharmacies to scan the barcode on every pack to confirm that the unique serial number is held in the database. All packs will also have a tamper evident seal and there is a requirement to check that the seal is intact prior to dispensing.

Where will the scan and tamper check take place?

The EU legislation requires the scan and tamper check to take place at "the time of supply to the patient". The NPA and other pharmacy organisations are working with the Department of Health to seek a pragmatic interpretation of this requirement. Pharmacy workflow and SOPs will need to be updated to account for FMD.

Who will fund all of this?

The database will be funded by the manufacturers. We believe that there will be a considerable cost to implementing and operating FMD within community pharmacies. As the FMD is a regulation imposed on community pharmacy by government, the NPA believes that it should be funded as part of the arrangements for NHS services. However, at this stage, no decisions relating to pharmacy funding have been announced.

Will the data generated be kept securely?

The NPA is a member of the stakeholder organisation that will oversee the FMD database, and we seeking to ensure that the confidentiality of all pharmacy data will be maintained.

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What are the implications of Brexit?

FMD comes into force before the UK leaves the EU, and therefore there will be a requirement to implement the directive in full by February 2019. Whether the same obligations remain after the UK leaves the EU depends on the outcome of the Brexit negotiations. It is worth noting that several non-EU countries (such as Norway and Switzerland) are also implementing FMD, and it is unlikely that the UK government would completely withdraw from a measure that is intended to improve patient safety. It is therefore likely that some form of FMD will be required in the long-term, regardless of the outcome of the Brexit process.

What do I need to do about this now?

Keep an eye on the NPA website and publications as information becomes available. At the moment there is little that pharmacies can practically do to prepare. However, if you are making a major change to the pharmacy, do think about how you may need to change your systems to incorporate FMD.

How to keep in touch with developments between now and February 2019

Please go to the FMD section of the NPA website for the latest information.

What is the NPA doing to influence FMD and support members in implementing FMD?

In addition to being part of the database organisation SecurMed UK, the NPA has established the UK FMD working group, whose membership includes all the main pharmacy contractor bodies across the UK (AIMp, CCA, PSNC, CPS, CPW and CPNI). This working group is engaging regularly with the Department of Health, the Medicines and Healthcare Products Regulatory Agency and the PMR suppliers seeking the most pragmatic approach to implementation of FMD.

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