Further information about the Falsified Medicines Directive (FMD). This is an area that ABPI has led for the sector and I have discussed with them.

FMD was designed as a EU-wide measure to ensure that medicines are safe, authentic and do not contain counterfeit or poor quality ingredients and remain inside of regulated supply-chains. An increase in the sophistication of falsified medicines increases the risk of them reaching patients and presents a serious threat to global health. FMD safety features legislation came into force on 9 February 2019, including in the UK.

The Falsified Medicines Directive (Directive 2011/62/EU) introduced measures such as:
- Obligatory safety features – a unique identifier and an anti-tampering device - on the outer packaging of medicines
- A common, EU-wide logo to identify legal online pharmacies
- Tougher rules on import of active pharmaceutical ingredients
- Strengthened record-keeping requirements for wholesale distributors.

In response, the pharmaceutical industry has made a significant investment to deliver FMD, since its launch in February 2019:
- 570 medicine manufacturers in the UK are connected to the system and are uploading information
- A standard coding system is now in place for eighteen thousand different medicine products
- 570 million individual packs of medicine have already been loaded on the UK system
- 67% of Community Pharmacies; 38% of medicine wholesalers; 36% of hospitals; and 8% of GP practices are now connected to the scheme.

Should the UK leave the EU without a deal in place, packs of medicines would be expected to have their unique code decommissioned on export from the EU. In a no deal the UK would be a third country and without negotiating access to EU databases (the central data hub underpins FMD safety features) will not be able to be part of FMD. Therefore, as part of the UK Government’s ‘no deal’ contingency planning, the UK Government has stated the UK would revoke the FMD Safety Features legislation. Regulatory obligations relating to FMD safety features would therefore cease to apply in the UK.

Recognising the need for continued vigilance against the real threat of counterfeit medicines entering the UK supply chain, the UK Government should reconsider its decision to revoke the FMD Safety Features legislation, working with the EU and EU stakeholders to maintain connection to the European Medicines Verification System or accelerate the establishment of a UK authentication system. The UK should seek for the EU to agree that the Falsified Medicines Directive will continue to apply in the UK, and that the UK can continue to access and input into the central data hub which underpins the FMD safety features.
The importance of FMD was recently demonstrated:

- MHRA has recalled in the UK some medicines Parkinson’s, epilepsy and blood clots that were taken out of the legitimate supply chain

- A falsified batch of a cancer drug has been discovered by a wholesaler in the Netherlands, in Bulgarian packaging – it has not yet been confirmed whether these were fake medicines. https://www.securingindustry.com/pharmaceuticals/more-fake-avastin-found-in-eu-thanks-to-fmd-scanning/s40/a10180/#.XRstFfZFyUk

The MHRA is the UK expert authority responsible for FMD and they would be able to assist with technical regulatory questions.

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