

Customer communication 23rd January 2019

EU Falsified Medicines Directive (2011/62/EU) Medicinal Product Safety Features

Dear Sir/Madam

We are contacting you to communicate our readiness for compliance to the above delegated regulation (EU) 2016/161 which comes into force in the UK in 2019.

Under this regulation, marketing authorisations holders (MAH) are required to ensure that specified prescription only medicinal product [see Annex I and II of the regulation for product exclusions/inclusions] meet new safety feature requirements; the deadline to implement these requirements is 9th February 2019. The new safety features require these products to have a unique identifier (2D data matrix code and human readable information) and anti-tamper evident features on the packing so that product validity and integrity can be monitored through supply chain up to supply to the patient.

Kent Express predominantly supplies persons authorised to supply medicinal product to the public and as such, in line with the Delegated Regulation Article 23, we will perform the necessary checks and decommission the product at despatch point to you. If however you are healthcare institution or pharmacy, or are a clinic operating within a host healthcare institution, please review your obligations and where required decommission product at point of use.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/767788/Additional_guidance_on_Article_23_HCI_s_and_Article_26.pdf

Should you need further information please contact me or refer to the recent UK Government guidance below which provides guidance and resources for all types of stakeholders in the supply chain as well as a link to the delegated regulation <https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features>.

Yours faithfully



Vicki Snow
Director Quality, Regulatory & Compliance/RP, UK & ROI