REGULATORY NEWS FEBRUARY 2019

EU NEWS

Safety Features:

As of 9 February 2019, most prescription medicines and some over-the-counter medicines for human use supplied in the European Union are required to have a unique identifier (a two-dimension barcode) and an anti-tampering device on their outer packaging. The anti-tampering device is a safety feature that shows whether the packaging has been opened or altered since it left the manufacturer, thereby ensuring that the content of the packaging is authentic.

The safety features are implemented through Commission Delegated Regulation (EU) 2016/161 that comes into application on 9 February 2019. It will apply in all EU/EEA Member States, except for Greece and Italy, who have until 2025 to update their already existing tracking systems.

In effect, this means that a Qualified Person (QP) certifying batches of medicinal products for human use that are within the scope of the Commission Delegated Regulation (EU) 2016/161, for these markets, on or after 9 February 2019, must ensure that the packs bear the unique identifier and anti-tampering device and that the batch data have been uploaded to the EU central repository.

Wholesalers must be able to verify the safety features present on such packs from 9 February 2019.

Brexit:

Brexit related guidances for companies is available on the EMA website: ema.europa.eu.

HPRA Batch Specific Requests:

A revised Guide to Batch Specific Requests for Human Medicines Version 3 has been published on the HPRA website.

FDA NEWS

Data Integrity and Compliance with Drug cGMP Questions and Answers:

The FDA have published a Guidance document on Data Integrity and Compliance with Drug cGMP Questions and Answers on their website in December 2018. The FDA addresses diverse data integrity topics in 18 questions and provides answers to these questions.