MHRA Drug Safety Update

January 2023

MHRA Regulating Medicines and Medical Devices

Electronic Prescribing and Medicines Administration Systems: report adverse incidents on a Yellow Card

The MHRA is asking healthcare professionals to be vigilant to adverse incidents involving software, apps, and artificial intelligence (AI) as medical devices and to report incidents to the MHRA via the Yellow Card scheme

Background

The term 'medical device' covers a broad range of products that are used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. Electronic Prescribing and Medicines Administration Systems (ePMAS) are used widely across the UK healthcare system and may qualify as medical devices.

The MHRA has been undertaking work with manufacturers of these ePMAS devices following the publication of the Healthcare Safety Investigations Board (HSIB) report on weight-based medication errors in children. This review was conducted following a case in which a child received a 10-times overdose of an anticoagulant medicine due to errors in the prescription, dispensing and administration processes. The HSIB noted that, although ePMAS are considered an effective way to reduce medication errors they may cause new technology-related errors.

The MHRA is asking for any potential errors with ePMAS to be reported to the MHRA, to help work with manufacturers to reduce these risks.

Report incidents on a Yellow Card

The MHRA has developed a version of the digital Yellow Card report form for suspected adverse incidents involving software as a medical device. Please select 'standalone software and medical device apps' in the drop-down menu to access the software medical device form.

Advice for healthcare professionals:

- be alert for potential errors occurring when using Electronic Prescribing and Medicines Administration Systems (ePMAS) which may lead to patient harm, especially errors involving the dosing of medicines or vaccines
- ePMAS and other software, apps and artificial intelligence intended to be used for a medical purpose are likely to be medical devices and any adverse incidents involving these devices should be reported to the MHRA's Yellow Card scheme
- use the new digital Yellow Card report form to inform us about adverse incidents involving software as a medical device