Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

FMD ALERT*

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 17 February 2020 EL (20)A/09 Our Ref: MDR 048-02/20

Dear Healthcare Professional,

Accord Healthcare Ltd.

Diamorphine Hydrochloride BP 100 mg Lyophilisate for Solution for Injection

PL 20075/0675

Batch Number	Expiry Date	Pack Size
F19160	05/2022	1× 5 Ampoules
F19161	05/2022	1× 5 Ampoules

Brief description of the problem

Accord Healthcare Ltd has informed us of an issue related to the expiry date for the above batches, which has not been encoded in 2D data matrix. Upon **FMD scanning verification and decommissioning** the product, errors such as: ***'Invalid barcode, missing required data elements'*** or ***"Scan failed"*** or ***"Invalid entry"*** will appear***.*** Due to difference in the end user systems; each system will display a different message from the NMVS Alert code, and this should be expected for these two batches only.

The human readable format is correct to the batch requirements and there are no concerns related to the product quality.

Advice for Healthcare Professionals

- Attempts to scan to verify or to verify and decommission the FMD 2D Data Matrix code on the pack will result in an 'Alert' or a failed scan. Please perform the usual checks for falsified medicines according to the FMD Source** guidance and dispense if deemed acceptable based on these checks.

- Due to inadequate supply of alternative products, the product is not being recalled. This issue only affects the batches listed above and all future batches will be corrected to avoid this error.

Company contacts for further information

For more information or medical information queries, please contact: Accord Medical Information Department on 01271 385257.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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London
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*Falsified Medicines Directive Alert
Falsified Medicines Directive (FMD) 2011/62/EU introduced new requirements to enhance the security of the European supply chain. Where the MHRA has identified risks to the security of the supply chain, FMD Alerts will be issued. For further information about FMD and safety features, please see this link on GOV.UK.

**FMD Source
The website of the UK FMD Working Group for Community Pharmacy
Please use this link for further information https://fmdsource.co.uk/
For the guidance see here. https://pharmacyfmd.files.wordpress.com/2019/03/fmd-interim-guidance-from-the-uk-fmd-wg-for-cp-v2.pdf.

Royal Pharmaceutical Society Guidance for members of RPS link here: https://www.rpharms.com/resources/ultimate-guides-and-hubs/fmd#alerts