

For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO Heads of Pharmacy and Medicines Management of HSC Trusts Regulation Quality Improvement Authority From: Chief Pharmaceutical Officer Mrs Cathy Harrison Castle Buildings Upper Newtownards Road Belfast BT4 3SQ

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Our Ref: PHC/9/2020 Date: 17 February 2020

FMD A L E R T* CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy Level

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.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

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Mrs Cathy Harrison Chief Pharmaceutical Officer



Working for a Healthier People