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| **Distribution:** | As Appendix 2 |
| **From:** | Chief Pharmaceutical Officer, Andrew Evans |
| **Date:** | 24 October 2019 |
| **Reference:** | CEM/CPhA/2019/28 |
| **Category:** | Class 2: Action With 48 Hours |
| **Title:** | Class 2 Drug Alert, Action Within 48 Hours, Pfizer Limited, Sayana Press 104mg/0.65ml Suspension For Injection |
| **For Action by:** | Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'<br>Community Pharmacists<br>Hospital pharmacies<br>Chief Pharmacists |
| **For Information:** | See Annex 2 – Distribution List |
| **What is this about:** | Full details are set out below. |
| **Why has it been sent:** | For your information, action and to pass on to colleagues. |

**Issue:**

Pfizer Limited is recalling selected batches of Sayana Press for subcutaneous (SC) injection due to the observation of injectors with moisture outside the sealed area with a wet label, immediately after their removal from the pouch and injectors with a temporarily unreadable expiry date on the unit label.

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website https://www.gov.uk/drug-device-alerts.

**Appendix 1**

To: Chief Executives of Health Boards and NHS Trusts

To: Medical Directors of Health Boards

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

To: **NHS Wales Shared Services Partnership to forward to:**

Dispensing General Practitioners

Community Pharmacists

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

# DRUG ALERT
## CLASS 2 MEDICINES RECALL

**Action Within 48 Hours**
**Pharmacy Level Recall**

Date: 23 October 2019 EL (19)A/28 Our Ref: MDR 055-06/19

Dear Healthcare Professional,

## Pfizer Limited

## Sayana Press 104mg/0.65ml PL 00057 / 1093

**medroxyprogesterone acetate suspension for injection**

| Batch Number | Expiry Date | Pack Size | First Distributed |
|---|---|---|---|
| L61367 | 31 January 2020 | 1 | 10 April 2015 |
| L61367Y | 31 January 2020 | 1 | 02 May 2016 |
| T34580 | 31 July 2020 | 1 | 08 November 2017 |
| X49124 | 30 June 2021 | 1 | 09 October 2018 |

**Brief description of the problem**
Pfizer Ltd has informed us of an issue related to the sealing process for some units of Sayana Press for subcutaneous (SC) injection potentially impacting the above listed batches. Sayana Press for subcutaneous (SC) injection is provided in a single-dose Uniject pre-filled injection system. During routine re-inspection of unreleased product batches, two related defects were observed;

- injectors with moisture outside the sealed area with a wet label, immediately after their removal from the pouch
- injectors with a temporarily unreadable expiry date on the unit label

The root cause analysis shows that the leak was attributed to a failure in the sealing process of the injection system and may impact the integrity of the product. Pfizer's health assessment of the issue concluded that the use of the impacted product has an unlikely probability of being associated with adverse events and the potential risk to patients is considered to be negligible.

**Advice for healthcare professionals**
Please quarantine all remaining stock of the above batches and return them to your supplier using your supplier's approved process.

Returns will be credited for all impacted product(s) against a Pfizer validated account up to a 12-week time frame from the start of the recall. No credits will be processed after the 12-week time frame from start of this recall.

Please do not consolidate any stock for return. All returns must be from the original delivery address. Any product(s) returned from non-Pfizer accounts will be retained by the distribution center and not returned. Credit for these returned products must be obtained from the supplier from where the product was purchased.