



Worldwide Biopharmaceutical Businesses

23rd October 2019

To whom it may concern:

UK Recall for Sayana[®] Press (medroxyprogesterone acetate 104mg/0.65ml suspension for injection in the Uniject[™] injection system)

Pfizer Limited is recalling the following batches of Sayana[®] Press (medroxyprogesterone acetate) 104mg/0.65ml suspension for injection from the UK market. This is because of an issue related to the sealing process of the injection system in some specific units in the listed batches.

Batches in scope of this recall:

F-Code	Batch Number	Expiry Date	Pack Size	First Distributed
F000016185	L61367	31 January 2020	1	10 April 2015
F000016185	L61367Y	31 January 2020	1	02 May 2016
F000016185	T34580	31 July 2020	1	08 November 2017
F000016185	X49124	30 June 2021	1	09 October 2018

Pfizer Limited, in conjunction with the **Defective Medicines Report Centre (DMRC)** of the **Medicines and Healthcare products Regulatory Agency (MHRA)**, have agreed to this recall.

Pfizer's 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.

We fully recognize the importance of Sayana Press to patients and physicians, and we place the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

Remaining stock of the above batches should be quarantined and returned to the original supplier for credit. Please liaise with your supplier or local branch of Alliance Healthcare.

All returns are requested to be completed by the 15/01/19.

No credit shall be provided for any product returned after this date.

Reporting of Suspected Adverse Reactions

You can assist us with monitoring the safety of Sayana Press (medroxyprogesterone acetate) 104mg/0.65ml suspension for injection by reporting suspected adverse reactions. Suspected adverse drug reactions (ADRs) should be reported via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For Medical information enquiries and to report adverse events or product quality complaints, please contact Pfizer Medical Information on 01304 616161.

Supply Update relating to recent Sayana Press out of stock

Pfizer Limited is aware of the current supply constraints related to this product and are diligently working with the MHRA to confirm the next batch of Sayana Press that is coming to the UK meets the high quality expected and safety requirements prior to making it available to order. We will be in a position to comment on dates for replenishing the market shortly.

Patients impacted or concerned should speak with their healthcare professional in the first instance.

Yours sincerely,

Samantha Howland
Medical Department
Pfizer Internal Medicine

Stock / Ordering Queries

If there are any outstanding queries in relation to stock, please contact the Pfizer Customer Contact Centre on 0845 608 8866.

Safety Reporting

Suspected adverse drug reactions (ADRs) should be reported to the MHRA <http://www.mhra.gov.uk/yellowcard>.
Suspected adverse drug reactions should also be reported to Pfizer Medical Information on 01304 616161.

Company contact point

For any questions or medical queries related to Pfizer products, please contact Pfizer Medical Information on 01304 616161 or visit <https://www.pfizermedicalinformation.co.uk/>