

To: All COVID-19 Vaccination Sites

24 October 2021

Dear Colleague,

We have been made aware of a potential issue with specific production lots of the El Dawlia ico Med - Sterile Hypodermic Syringe with Combined Safety Needle manufactured by International Medical Supplies (IMS) Euro Ltd. Specifically lot numbers 2105 and 2106.

There have been no reports of patient harm but IMS has issued a Field Safety Notice (FSN) to voluntarily recall these products. You may have already received the FSN and an accompanying note from UKHSA. This communication supersedes the note issued by UKHSA.

DHSC, UKHSA, MHRA and NHS England and NHS Improvement have reviewed the FSN issued and conducted a thorough risk assessment. The FSN relates to:

- A small amount of additional lubricant in the barrel and/or luer tip of the syringe. This may make the lubricant visible in the luer tip. The fluid is entirely safe and a normal constituent and does not affect the delivery of the vaccine. However, where it is visible, the entire unit should not be used and another opened.
- Occasionally, syringes and/or needle may be upside down within the package meaning users may inadvertently hold the wrong end of the product and therefore increase risks of not maintaining aseptic technique. As this could be the case with these syringes or needles, please take extra care when opening the packaging to maintain aseptic technique.

Where alternative suitable products are available please use these until all product replacement is complete. If it is not possible to use an alternative, vaccinations using the products identified should continue. From a clinical perspective, the assessment undertaken by UKHSA indicates that the risk of delaying vaccinations for patients far outweighs the issues identified by the FSN, along with the steps outlined above.

UKHSA will be continuing to replace the impacted products and will be issuing a priority push of alternative products to sites that have received batches of the products identified by the FSN early next week.

Yours sincerely,

A handwritten signature in purple ink that reads "Jennifer Harries". The signature is written in a cursive, flowing style.

Professor Jennifer Harries OBE
Chief Executive Officer
UK Health Security Agency