# Supply problems with total parenteral nutrition (TPN) bags – Calea UK site in Runcorn, Cheshire

**Overview**

The MHRA performed a routine inspection of Calea UK at its registered site in Runcorn on 24-26 June 2019. During the inspection, problems were identified with the design of the manufacturing process for total parenteral nutrition (TPN) bags that did not meet the requirements of guidance published by MHRA.

MHRA has a responsibility to ensure the safety of medicines supplied to UK patients. A key part of our work is carried out through regular inspections of UK manufacturing sites.

Total parenteral nutrition (TPN), also known as parenteral nutrition (PN) is a form of nutritional support given via the bloodstream, with an IV pump. Many of the products manufactured at the Runcorn site are made and delivered to meet the needs of individual patients, with intestinal failure.

**Action taken by the MHRA**

When our inspectors identified this issue, we requested that Calea take immediate action to change their manufacturing process to ensure compliance with the MHRA's published standards. This has led to a reduction in output while they consider longer term changes to their processes.

Whilst no defective products have been identified to date, the changes to the production process are a precautionary, but necessary measure, needed to ensure product safety is maintained.

**Background**

From a sample taken by Calea on 25 June as part of Calea's routine monitoring designed to detect microbial contamination in the production area and on production personnel, bacteria of the type Bacillus cereus / thuringiensis / mycoides were recovered.

The equipment used for identification is not sufficiently sensitive to identify the exact type of bacteria, so in these situations we expect the facility to address the worst-case organism, which would be Bacillus cereus. These bacteria are known human pathogens, which is of particular concern for the many vulnerable patients receiving parenteral nutrition.

Even though this contamination was found in the production area, it is important to add that we found no evidence to indicate that the products manufactured and supplied to patients during this period were contaminated.

This contamination, in combination with our inspectors identifying that

production processes were not in compliance with MHRA guidelines dating from 2015 presented a potential risk to patients and caused us to take immediate action to instruct the company to implement important changes.

We understand this has caused concern for many patients, and these are not decisions we take lightly. However, our priority at all times must be patient and product safety.

**Progress to date (updated 26 July 2019)**

It is vital that patients can get their parenteral nutrition quickly.

We are working closely with the company to safeguard the quality and safety of these important products, with MHRA inspectors monitoring changes to the production process, through correspondence and regular inspection visits.

Following the inspection, Calea reduced output in order to make necessary changes. Whilst there is a backlog in production, Calea is working to rectify the problem and increase supply as soon as possible.

In addition to restoring production at the site, alternative supply options are being explored as a matter of urgency by a national group of experts convened by the Department of Health and Social Care (DHSC). The MHRA is providing regulatory assistance to this process.

Information is being provided by the DHSC expert team to NHS Trusts, so patients should contact their prescribing consultant for next steps on supply arrangements.

**Further information**

Inquiries about the role of the MHRA:

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