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NHS England and NHS Improvement
Skipton House, 80 London Road
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19 December 2019

Dear patient and/or carers,

We are writing to you as a patient or carer of someone who uses parenteral nutrition. We know that this has been a difficult time for you and this letter is to update you on the current situation following the disruption in production from the provider Calea.

As you know during an inspection in June 2019, the Medicines and Healthcare products Regulatory Agency (MHRA) identified problems with the manufacturing and environmental monitoring process and therefore, the MHRA insisted that Calea make some changes to their parenteral nutrition (PN) making process to make sure that the quality of the PN bags they produce continue to be of the expected high standard.

The NHS is continuing to work with our partners and Calea to resolve the situation and we know that your clinical team is working hard to support you through this time.

We are writing to update you on the situation:

- Production levels have improved but Calea is still working to make the required changes, with production not expected to be at full capacity for several more months.
- Calea are continuing to work with us, the Department of Health and Social (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) to increase supply, whilst ensuring that patient safety is not compromised.
- At NHS England and NHS Improvement we are undertaking longer term work to consider how the service and the supply of parenteral nutrition can be strengthened in the future.

Updated frequently asked questions web page (FAQs)

NHS England and NHS Improvement



Working with the patient group PINNT we have updated and added further questions to the web page containing frequently asked questions:

<https://improvement.nhs.uk/resources/supply-issue-to-people-on-home-parenteral-nutrition-from-calea/>

This page will be updated again in January 2020 and we will also aim to write to you again in January.

How long this situation is likely to continue for:

Whilst production levels at Calea have improved, the situation is expected to continue for several months. Calea is continuing to work us, the Department of Health and Social Care (DHSC) and the regulatory body the Medicines and Healthcare products Regulatory Agency (MHRA) to improve production capacity as soon as it is safe to do so.

The national regulatory body, the MHRA, which is responsible for ensuring that Calea meets the required quality and safety standards, is maintaining oversight of the production site to ensure the changes to their production processes meet these standards. The team managing this incident at NHS England and NHS Improvement includes clinical experts and we are working with our partners to ensure that safety for patients is a number one priority. Please be assured that we are doing everything we can to resolve this situation for you and future patients.

Recent issue with some deliveries

There may still be occasions when your delivery arrives in two parts for example if your ancillaries need to be sent separately. Calea have confirmed they will contact affected patients directly if this occurs. We understand that when this happens it is inconvenient for you and we are continuing to have regular calls with Calea to closely monitor the deliveries and to prevent this as much as possible.

Christmas and New Year holiday period

Calea is working with hospital trusts to ensure that there is no disruption to your deliveries over the holiday period. The Calea production site is operational seven days a week and is only closed for one day on Christmas Day.

Calea's 24-hour patient advice line will be open throughout the holiday period including weekends and bank holidays, should you need to contact your Calea homecare nurse or have any questions about your deliveries. The helpline is open 24 hours a day, seven days a week.

Calea's 24-hour patient advice line: **0800 121 8300**



Securing the supply of parenteral nutrition in the long-term

We recognise we need to avoid a repeat of Calea's problems, so work is underway to examine longer-term solutions for the supply of parenteral nutrition to NHS patients.

The production of medicines and medical products including home parenteral nutrition (HPN) is complex and highly regulated. Materials and processes must meet rigorous safety and quality standards. In England there are only a few manufacturers of parenteral nutrition and when one supplier experiences a problem with production such as the issue with Calea, it creates further pressure on the whole supply chain.

Whilst addressing the long-term supply issue with HPN for NHS patients is complex, we are working with DHSC, NHS trusts, clinical experts and suppliers to explore a number of options. These include a review of the care that you receive from the hospital through to the care you receive at home, and a review of pharmacy aseptic services in England, which the DHSC commissioned NHS England and NHS Improvement to undertake. The aim of the review is to develop recommendations to deliver a high quality, safe and resilient service able to meet both current need and cope with the increase in demand for aseptic production of chemotherapy, parenteral nutrition and other medicines.

We are also continuing to work with other suppliers of parenteral nutrition to see where they can increase production now and in the future.

Please be assured that we are doing everything we can to help Calea to resolve their production problems as quickly and as safely as we can. We are working with your local nutrition support team and you should continue to contact them if you have any concerns or questions about your treatment.

Yours faithfully



Felicity Cox

Director, NHS incident management team

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