

PINNT
PO Box 3126
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Simon Stevens
Chief Executive
NHS England

23rd July 2019

Dear Mr Stevens

Total Parenteral Nutrition – Supply chain issue to patients – Fresenius Kabi / Calea

I am sure you are aware of the current issues following the MHRA directive to Fresenius Kabi (FK). As a background FK own a home parenteral nutrition service (HPN) called Calea which is a subsidiary of FK. Calea/FK are one of the six national providers of HPN recognised by NHS England.

Following a routine MHRA visit, the way trace elements and vitamins were added during the compounding process was changed with immediate effect. As a support charity we are clearly advocates for patient safety in all aspects of the PN production and care.

Sadly, this directive has meant that production of PN has been severely reduced and we are seeing no improvement in capacity; in fact, it is being reduced further. Patients on this life sustaining therapy are not getting the medication that they require; this is both adults and children. As you will appreciate these patients/parents/carers are fully aware of the consequences of not receiving essential nutrition and hydration; this is having an enormous impact on them clinically, mentally and physically.

Some patients are being admitted to hospital as the only way to treat them. This is far from ideal as they should be able to have their treatment in the home setting as usual. It is a massive burden on already busy hospitals and healthcare professionals, let alone the people and families its affecting.

As a patient support group, we are of course solely concerned about the patient sector this is currently affecting, and we would ask for your help resolving this matter as well as the following points:

Registered charity **1157655**



PINNT: "Supporting people on home artificial nutrition"

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- 1 Extensively improve communication to the patients/parents/carers – sadly most are going from day to day unaware if, and when they may receive PN
- 2 Improved coordination between all stakeholders (NHS England, PN provider, treating team and patient representation) to create transparency and accountability. While we recognise there are approval processes in place for all communications, these need to be fast tracked as a matter of urgency
- 2 Appropriate contingency for patients on this high tech and complex therapy for the coming days and weeks, with a view to a long-term plan being prepared.

We are copying this open letter to the Department of Health and Social Care, Medicines and Healthcare Products Regulatory agency (MHRA and FK/Calea. In addition, we will be publishing a copy to our members.

We look forward to hearing from you and or your team in due course, but we urgently call upon your help to resolve this situation for the patients, parents and carers.

Yours sincerely

Carolyn Wheatley

cc.

Niamh Furey, Managing Director UK and Ireland Fresenius Kabi
Lynn McCready, Business Unit Director Calea & Nursing
Baroness Blackwood, Parliamentary Under Secretary of State, DHSC
Dr Ian Hudson Chief Executive of the MHRA
BAPEN President, Dr T Smith
Lord Prior, Chairman NHS England
Department of Health and Social Care, DHSC

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