



Department
of Health

For the Attention of the Medical Director

URGENT FOR ACTION

10 April 2015

Re: SUPPLY DISRUPTION - Baxter Colleague pump compatible IV administration sets

Baxter Healthcare has notified us that they are currently experiencing a shortfall in the supply of a number of Colleague pump compatible IV administrations sets and that this situation will continue until July 2015.

To maintain availability of Colleague pump compatible administration sets during the period of this supply disruption it is essential that all trusts using the Baxter Colleague infusion pump system make the following changes in practice, with immediate effect:

- 1) 'One Set System IV administration sets (Baxter C96 product codes) should only be used for pumped infusions through a colleague pump.
- 2) For gravity infusions, where you currently use the 'One Set System IV administration sets', you should use an alternative gravity IV administration set (details of alternative gravity IV administration sets are available through NHS Supply Chain).
- 3) Where alternative infusion pumps are available and appropriate, these should be used in preference to the Colleague pump.

By taking this action promptly across all trusts, this will relieve demand on the affected products.

It is estimated that the supply of administration sets from Baxter would then be sufficient to ensure that Colleague pump compatible sets will be available for the administration of pumped infusion.

However, availability of stock for distribution to trusts will remain extremely tight over the coming month, even accounting for changes in practice as proposed within this communication.

In view of this, a range of additional actions are recommended for trusts to take, as set out in the notification below.

The Department of Health and NHS England have initiated a national supply disruption response to co-ordinate activity and communications across different areas of the system. To assist this team in understanding the latest stock position, and the extent to which trusts are reliant on the Baxter Colleague pump system, an initial data collection mechanism has been established utilising the Centre for Procurement Efficiency portal (that is available to all procurement / supplies colleagues in NHS provider organisations).

The availability of this data collection system, and details of how to access this, will be communicated to all Heads of Procurement directly within the next 24 hours.

Prompt and regular completion of this information return by your trust, will greatly assist the national supply disruption response team to identify where problems are developing, and where exceptional support or interventions might be required.

Can I ask that you make arrangements within your trust to take immediate action on this issue, to mitigate against the significant risk that this supply disruption issue poses to patient safety and the continued delivery of high quality care.

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Supply Disruption Notification

Baxter Colleague pump compatible IV administration sets

Baxter Healthcare has notified us that they are currently experiencing a shortfall in the supply of a number of COLLEAGUE pump compatible IV administrations sets. This is due to a prolonged period of increased demand and difficulties in ramping up component supply.

The Department of Health and NHS England recognise the serious nature of this issue and have initiated a national supply disruption response to co-ordinate activity and communications across different areas of system. Separate communications are being issued on this matter to Medical Directors, Directors of Nursing, EPRR Leads and Critical care Networks.

Three product lines are affected by this supply issue: FSB835, FSB144 and FSB1246.

NPC	MPC	Product Description
FSB835	EMC9608	Pump/gravity solution administration set, non-vented, 15µm filter, Y-injection site, basic male Luer
FSB144	RMC9615	Pump/gravity solution administration set, vented, 15µm filter, basic male Luer
FSB1246	MMC9667L	Pump/gravity solution administration set, non-vented, 15µm filter, Clearlink Y-site,

The fastest moving of these lines FSB835/EMC9608, supply will continue but a shortfall situation is predicted through to the end of June 2015, necessitating the need to use alternative products for gravity infusions.

For the other two product lines it is expected that normal supply will be resumed at the end of April 2015, however in the interim period there will be a need to use alternative products to alleviate pressure on existing stocks.

Further details on the suggested alternative product use associated with each of the product lines is provided at the bottom of this notification.

Baxter is working closely with both customers and NHS Supply Chain to facilitate the adoption of alternative products and ensure the continued availability of products when and where they are needed.

Immediate Action Required

As stocks during this period will not be sufficient to meet all gravity and pump administrations **the following action is urgently required:**

- 1) 'One Set System IV administration sets (Baxter C96 product codes) should only be used for pumped infusions through a colleague pump.
- 2) For gravity infusions, where you currently use the 'One Set System (Baxter C96 product codes) you should use an alternative gravity IV administration set (a list of alternative gravity IV administration sets can be viewed by clicking here).
- 3) Where alternative infusion pumps are available and appropriate , these should be used in preference to the Colleague pump.
- 4) Trusts should assess and monitor their requirements and inventory levels, for affected products.
- 5) Trusts should identify a procurement lead to manage and co-ordinate the procurement and materials management response, and to take responsibility for the completion of the information return on stock levels, predicted demand and equipment, via the Centre for Procurement Efficiency portal.
- 6) All relevant procurement, materials management and clinical staff should be notified of the supply issue and advice being provided on management of this issue. Ideally, have Lead Nurses communicate to clinical colleagues the issues around shortage of lines.
- 7) Trusts should not to exceed normal demand requirements, and should reduce demand of 'One Set System IV administration sets (Baxter C96 product codes) to reflect the reduced usage arising as a result changes in clinical practice, as recommended.
- 8) Trusts should identify a single requisition point to place all orders against, for the period of supply disruption and to nominate a single individual to liaise with NHS Supply Chain regarding stock availability and the trusts requirement. If you require assistance with this, then please contact Donna O'Rourke (contact details below)
- 9) Where possible, trusts should pull all their stock of FSB835 and hold in a central location, releasing only to areas that have a specific clinical need.
- 10) Trusts should assess the extent to which Colleague pump systems are used in the trust and identify critical areas of care that are heavily reliant on Colleague pumps.
- 11) Trusts might need to consider the option of leasing, renting or purchasing new pumps to mitigate against significant risks to patient care. Where you identify a need to acquire new infusion pump capacity, then please communicate this to the NHS Supply Chain customer

service team who will co-ordinate requests with the National Supply Disruption Response team.

12) Seek advice and support directly from your local Baxter representative.

Contacts and Communications

NHS Supply Chain in conjunction with Baxter will manage the allocation of product to where need is greatest and work with you to assess your requirements and to try to provide alternative options to maximise availability of stock. It is imperative to stress that **a successful outcome is totally dependent upon the cooperation and support of trusts in quickly adopting the guidance outlined.**

Donna O'Rourke will lead NHS Supply Chain's allocation of products. Donna can be contacted directly via donna.orourke@supplychain.nhs.uk or telephone 01928 858565

Where trusts believe that there is significant risk to patient safety, resulting from this incident, then they should notify their trust Medication Safety Officer / Medical Device Safety Officer at the earliest opportunity to escalate the issue.

We will continue to keep you updated until normal supply resumes.

Alternative Products and Mitigating Actions

Alternative products and mitigating actions for each affected product line, are shown in the table below.

NHS Supply Chain NPC	Baxter Product code	Description	Mitigating Actions
FSB835	EMC9608	Pump/gravity solution administration set, non-vented, 15µm filter, Y-injection site, basic male Luer	Adopt a suitable alternative administration set for all gravity infusions (click here for list of options) Follow other recommended action in this ICN to reduce and manage demand.

FSB144	RMC9615	Pump/gravity solution administration set, vented, 15µm filter, basic male Luer	<p>Adopt a suitable alternative administration set for all gravity infusions (click here for list of options)</p> <p>Use EMC9608 as an alternative where preparations are being drawn up from flexible containers (where venting is not required).</p>
FSB1246	MMC9667L	Pump/gravity solution administration set, non-vented, 15µm filter, Clearlink Y-site,	<p>Adopt a suitable alternative administration set for all gravity infusions (click here for list of options)</p> <p>Use EMC9608. If needle-free bolus port is required, must be used with a needle-free extension set.</p>

Alternative product codes provided above are being suggested on the basis of sufficient stock and ongoing availability. Trusts should consult with the customer service team at NHS Supply Chain prior to ordering other Baxter product codes that they may believe are viable alternatives for delivering pumped infusions via the Colleague pump, as it is likely that this will create shortages across a wider range of product lines.