

**National Pharmaceutical Supply Group (NPSG) Communication:
Making best use of restricted aseptic compounding capacity**

In order to assure patient safety, the MHRA has recently taken regulatory actions against some commercial aseptic compounders placing limitations on their aseptic compounding activity. This is in addition to the constraints supplier's planned and unplanned maintenance is placing on the system. This has led to restrictions on their capacity to accept new business and extended lead times for some existing business.

It is essential that NHS customers of these services review their local activity and practices to ensure that the available services can support as many NHS patients as possible across the country. All pharmacy teams under the leadership of Chief Pharmacists should consider how best to manage the continued challenges to services for supply of aseptically prepared injectable medicines.

The NHS Improvement review of aseptic services which reported to Keith Ridge in April 2018 is being progressed through the Medicines Value Programme Board and the strategic actions are expected in the autumn. This review will not provide a "quick fix" to the current challenges however it will be critical to identifying and securing essential medium to long term system-wide changes to facilities, services & service efficiency together with staffing and associated logistics.

Suggested immediate actions:

1. **Prioritise local aseptic pharmacy capacity** for short shelf-life, very expensive and genuinely clinically urgent items ahead of long shelf life, less urgent items which could be batch manufactured.
2. **Ensure continuing engagement and effective communication between teams (medical, pharmacy & nursing).**
 - This is vital to manage the current situation safely, efficiently and maximising the quality of care. The wider healthcare team should be aware that aseptic compounding capacity available to the NHS is a finite resource that is directly influenced by their practice. Local clinical engagement is critical to maximising the opportunity to use batch-manufactured products in preference to patient specific products which represent least efficient use of capacity.
 - Recognise that for non-NHS suppliers to work efficiently and minimize costs, they must be able to plan their workload **just as our own units do**. This places the onus on NHS customers to plan the care processes that generate the demand for these products.
3. **Ensure that priorities for use of aseptic compounding be they outsourced or local within the NHS are focused on continuity of care and patient safety** and are considerate of the wider NHS needs.
4. **Minimise reliance on patient specific (bespoke) products.** Bespoke and short turnaround time product demand reduces commercial supply capability to deliver batch produced products. Trusts should be aware that short turnaround services will carry a disproportionate cost and contribute to reduced efficiency and supply capacity.
5. **Use licensed ready to administer products wherever possible.** Examples of where immediate efficiencies might be gained include methotrexate sc – one manufacturer is preparing 8000 doses per year when this is available as a licensed medicine. Gemcitabine is available as a licensed ready to administer infusion.

PROTECT – MANAGEMENT

6. **Maximise the use of dose banding, rounding and use of standardised products** to support the most efficient and cost-effective use of all available compounding capacity. For example dose banded chemotherapy, standardised parenteral nutrition. As an example, infliximab can be dose banded; one supplier is preparing 1000 bespoke doses per month.
7. **Priorities for use of third party capacity should be determined jointly by NHS customers and suppliers and not by suppliers alone.** Suppliers should be encouraged to manage capacity by capping activity and not by extending lead times and discuss their plans with the regional procurement specialists.
8. **Work collaboratively with national procurement colleagues** to ensure that the NHS is able to, with confidence agree priorities with compounding units. This will ensure that available compounding resources are allocated fairly across the NHS. This process should be co-ordinated by the regional medicines procurement specialists.
9. **Trusts must not seek to negotiate local agreements** without liaison with the regional procurement specialists or beyond services covered by contracts or service level agreements already in place.
10. **Ensure that assessment of risks are documented,** updated and maintained within NHS organisations which are supporting the above
11. **Act in the best interests of the NHS** and follow the general principles of good practice which apply to the management of any medicines shortage

There is a finite amount of aseptic capacity nationally. Chief Pharmacists are responsible for ensuring that adequate contingency planning is in place to ensure patient safety and continuity of care in the event that any major supplier's service is suspended or severely curtailed for any reason.

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