

Who are the Independent Aseptic Compounders?

BSNA represents the commercial manufacturers, 'Independent Aseptic Compounders', of aseptically prepared injectable solutions which are used to meet specific patient needs in the treatment or management of a range of diseases, disorders or medical conditions. These solutions include chemotherapy, parenteral nutrition and Central Intravenous Additive Services (CIVAS), and are often referred to as 'specials'.



What is aseptic preparation?

Aseptic preparation is the manipulation of sterile starting materials and components in such a way that they remain sterile and uncontaminated whilst being prepared for presentation in a form suitable for administration to patients. Aseptic techniques aim to prevent pathogenic organisms from being introduced to susceptible sites by the user, environment or equipment. IV solutions are prepared using carefully defined aseptic techniques and processes to avoid contamination. These techniques and processes are performed in high-grade cleanrooms where measures such as clean clothing, non-touch techniques and environmental air filtration are implemented.

What solutions are aseptically prepared?



Parenteral Nutrition (PN)

The provision of nutrition to patients intravenously (via the veins) in the form of a liquid infusion.



Chemotherapy

The use of cytotoxic (anti-cancer) medicine to treat a disease.



Central Intravenous Additive Services (CIVAS)

Any preparation which is manipulated aseptically to create a ready-to-use injectable medicine, e.g. antibiotics or pain relief.

Regulation

All Independent Aseptic Compounders hold a manufacturing specials licence issued by the MHRA – the UK body responsible for the regulation of medicines and medical devices. This licence permits the compounding of medicines which are referred to as 'specials'. Specials are manufactured specifically at the request of a prescriber when there are no suitably licenced medicines available that will meet a specific patient's needs. To ensure that these specials are safe and efficacious, manufacturers comply with relevant legislation and guidance, and are subject to regular inspections by the MHRA to maintain high quality standards and retain their manufacturing specials licence.



The Independent Aseptic Compounders sector is a valued partner of the NHS and supplies **over 50% of aseptic compounding capacity in the UK.**

The sector delivers approximately 4 million units of chemotherapy, parenteral nutrition and CIVAS annually.



The value of the sector

The Independent Aseptic Compounders sector is a valued partner of the NHS and plays a key role in ensuring that patient specific treatment needs are met.

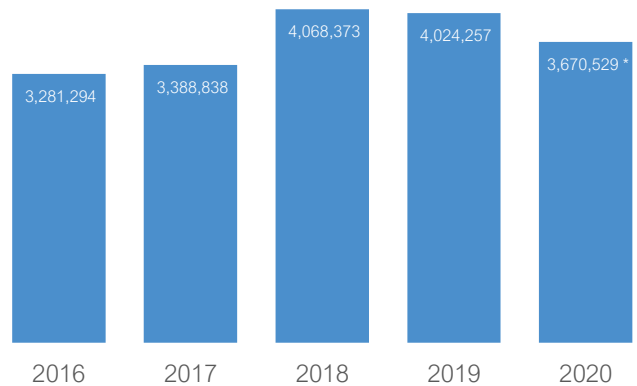
Some NHS Trusts possess the infrastructure and capacity to meet all or some of their aseptic requirements. Where they do not, the preparation of specials is outsourced. The Independent Aseptic Compounders provide additional aseptic capacity and relieve pressure on the NHS; the sector is proud to support patients in partnership with the NHS.

Meeting increasing demand

BSNA's member companies have demonstrated an ability to adapt to increasing demand for aseptic services and continue to work closely with the NHS to ensure that patient needs are met.



Independent Aseptic Compounders Volume Trend 2016-2020 (units)



*2020 volume reduction due to disruption of normal NHS services and subsequent decrease in demand in specific patient treatment areas.

Key priorities for industry

- ⇒ The Independent Aseptic Compounders have an integral role, as a key supplier of specials, in the delivery of safe, efficient and resilient aseptic services to meet current and future patient needs, working in collaboration with the NHS.
- ⇒ The regulation of aseptic compounding must be proportionate and applied to a uniformly high standard across the NHS and commercial sectors.
- ⇒ Industry has demonstrated an ability to respond rapidly to increased demand and a willingness to invest, with capital expenditure averaging £14.5 million per year over the past four years.

BSNA represents Bath ASU, Baxter Healthcare, B. Braun, Fresenius Kabi, ITH Pharma, Lloyds Pharmacy Clinical Homecare, Quantum Pharmaceuticals