Clinical Landscape and Impact on Aseptic Capacity

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Contents & Introduction

- Drug development in the UK
- Oncology treatment recently approved by NICE
- Horizon scanning: bispecifics, CAR-T and reformulation
- Medicines value and biosimilars
- Commercial sector
- Impact on aseptic production units

Is the drug development pipeline slowing down?

When it comes to the drugs industry, Britain is suffering withdrawal symptoms.

This year, three of the
Merck, AstraZeneca, a
investments worth alr
specifically the NHS d
risk".

Open access Original research

JK lost its position as a
on for world-leading clinical
' A comparative analysis of
r clinical trials
Brexit

Wes Streeting's row with pharma firms grows as they reject NHS drug pricing offer

Britain | Big Pharma

Drugmakers fail to meet health secretary's latest offer, meaning 'unsustainable' rebate scheme will stay in place

ma as
expectedly

AstraZeneca's fall
Britain

The country's largest listed company is a

high VPAG payback rate in 2025

Once VPAG was introduced in early 2024, the initial headline payback value was only 15.1% for newer medicines in Q2–Q4.

GlobalData. | Janet Beal | GlobalData. | Alex Watt | December 20, 2024

Is the drug development pipeline slowing down?

- Cancer Drug Fund reformed in 2016
- Increased regulatory burden for clinical trials
- Innovative Medicines Fund for non-cancer treatments launched in 2022 and reformed in 2024
- 14 medicines have passed through IMF into baseline funding
  - Three cancer adjacent approvals; GvHD, cisplatin induced hearing loss
  - Nine active approvals for five medicines
- Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) in current form until 2028

Recent NICE Technology Appraisals

Drug	Clinical Area	Category	Combined with?	Therapy
Enfortumab vedotin	Urothelial cancer	Antibody-drug conjugate	Pembrolizumab	New drug
Pembrolizumab	Endometrial cancer	Monoclonal antibody	Carboplatin & paclitaxel	Expanded license
Tremelimumab	Hepatocellular cancer	Monoclonal antibody	Durvalumab	New drug
Fruquintinib	Colorectal cancer	Kinase inhibitor	Oral monotherapy	New drug
Zanabrutinib	Lymphoma	Kinase inhibitor	Oral monotherapy	Expanded license
Belantamab mafodotin	Myeloma	Antibody-drug conjugate	Bortezomib & dexamethasone	New drug
Ribociclib	Breast cancer	Kinase inhibitor	Aromatase inhibitor	Expanded license
Nivolumab	Colorectal cancer	Monoclonal antibody	Ipilimumab	Expanded license
Durvalumab	Endometrial cancer	Monoclonal antibody	Platinum chemotherapy	Expanded license
Dostarlimab	Endometrial cancer	Monoclonal antibody	Platinum chemotherapy	Expanded license
Capiversitib	Breast cancer	Kinase inhibitor	Fulvestrant	New drug
Osimertinib	Endometrial cancer	Kinase inhibitor	Pemetrexed & platinum chemotherapy	Expanded license
Erdafitinib	Urothelial cancer	Kinase inhibitor	Oral monotherapy	New drug
Brentuximab vedotin	Lymphoma	Antibody-drug conjugate	AVD chemotherapy	Expanded license

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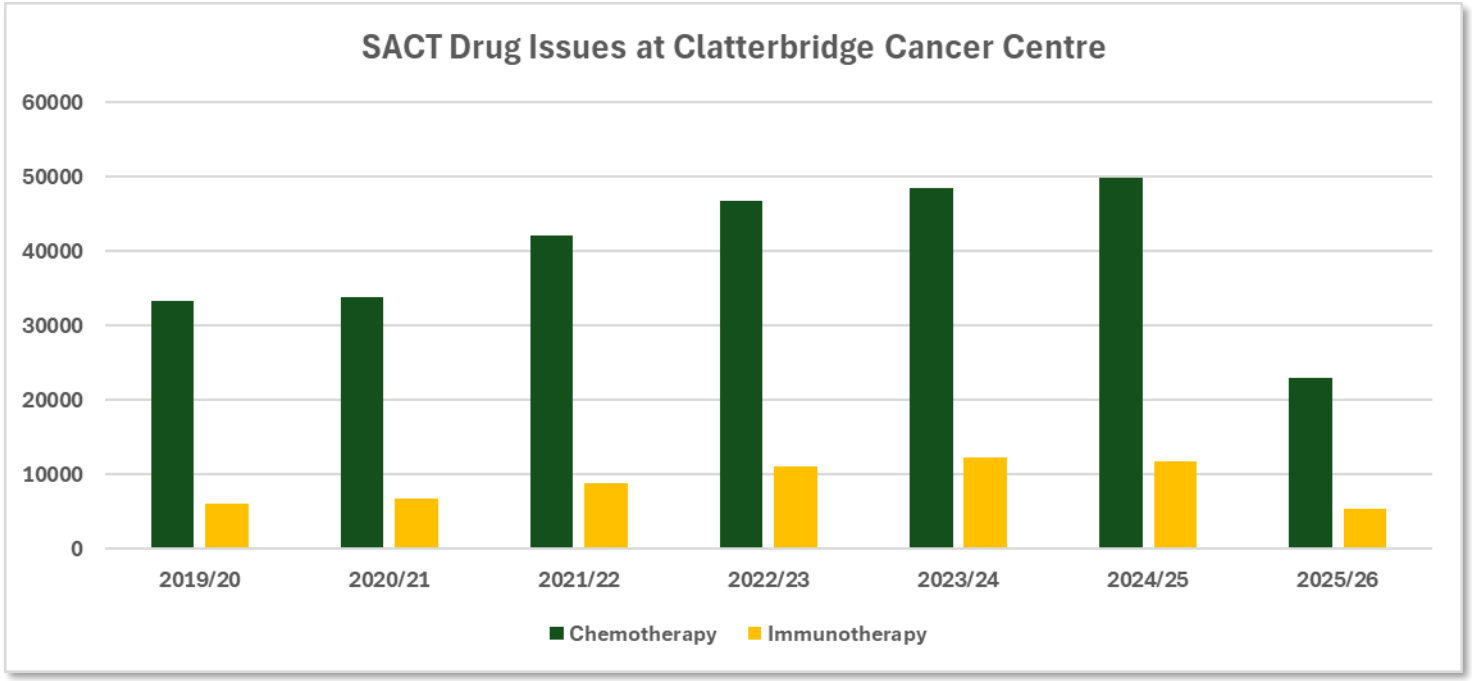
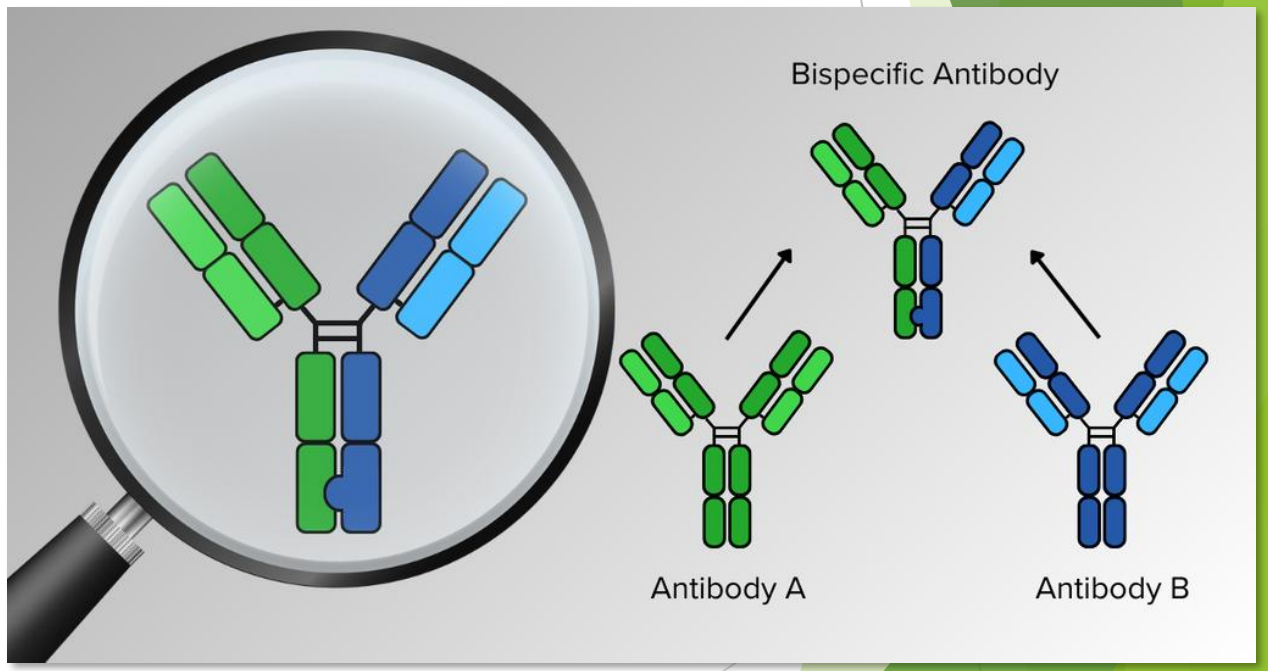
Direction of Travel



	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26
Chemotherapy	33,339	33,889	42,105	46,732	48,550	49,968	22,945
	85%	83%	83%	81%	80%	81%	81%
Immunotherapy	6,062	6,769	8,834	11,066	12,297	11,774	5,418
	15%	17%	17%	19%	20%	19%	19%

Bispecific antibodies

- Next generation of immunotherapy
- Unlike ‘traditional’ monoclonal antibodies that bind to one target, bispecifics bind to two different targets
- Often associated with CRS and ICANS
- Usually involves titration doses given close together until patient is established on treatment
- Some given subcutaneously at fixed maintenance doses – potential for near patient preparation?



Bispecific antibodies

2017 Blinatumomab

2018 Emicizumab[#]

2019 Blinatumomab

2022 Amivantamab, mosunetuzumab, faricimab[#]

2023 Glofitamab

2024 Teclistamab, epcoritamab, elranatamab

2025 Tebentafusp

2026+ Talquetamab, amivantamab, glofitamab, elranatamab, epcoritamab, mosunetuzumab

Non-oncology indications

Negative appraisal

CAR T-cell therapy

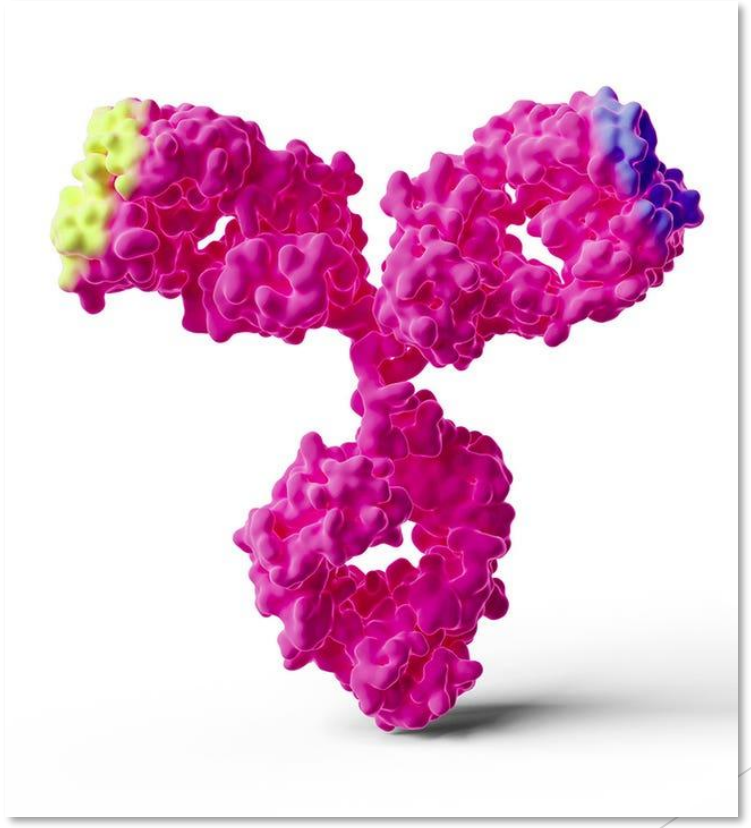
- Chimeric antigen receptor T-cell therapy approved for use in leukaemia and non-Hodgkin lymphoma
- Treatment only available in approved specialist centres
- Four therapies currently approved:
  - Yescarta® (Axicabtagene ciloleucel)
  - Breyanzi® (Lisocabtagene maraleucel)
  - Tecartus® (Brexucabtagene autoleucel)
  - Kymriah® (Tisagenleucleucel)
- Significant burden on aseptic preparation of time sensitive conditioning chemotherapy

Key Oncology Molecules

- Launch of biosimilar products governed by several market factors
- Market protection, exclusivity and originator patent expansion can delay launch of biosimilar products
  - Perjeta® (pertuzumab) expiring 2025
  - Yervoy® (ipilimumab) expiring 2026
  - Adcetris® (brentuximab) expiring 2026
  - Opdivo® (nivolumab) expiring 2028
  - Keytruda® (pembrolizumab) expiring 2028
- Subcutaneous nivolumab launched this summer, pembrolizumab expected early 2026

Medicines Value - Biosimilars

- Utilising biosimilars is now well-established concept within medicines value
- Switches are frequently benchmarked at regional level
- Significant financial incentives for rapid adoption of key molecules
- Cost saving opportunities with biosimilar-to-biosimilar switches
- Where are savings realised?



Medicines Value - Biosimilars

- Well established, older therapies tend to be block funded
- Savings on block medicines are retained locally
- Newer, patented high-cost therapies tend to be directly funded
- Savings on passthrough drugs are (largely) retained by commissioners
- Collaboration with technical services around product selection
- Balancing several factors; cost, volume, capacity, expiry

Clatterbridge Example: Rituximab

- Five rituximab vial preparations available on local framework
- Cheapest option not available on framework as pre-mixed bag
  - 620 vials – Potential saving of £15 per vial
  - 304 pre-mixed bags – Mark up of £20 per bag
  - Potential saving circa £16,000
- Impact on aseptic unit capacity?
- Impact on clinical service?

Commercial Capacity

- Range of commercial providers offering batch and bespoke patient specific services
- Production on-costs will largely be covered by commissioners for passthrough drugs
- Large volume block drugs associated with significant on-costs
  - Paclitaxel, oxaliplatin, carboplatin
  - Outsource oncost around £500k per year
  - Should we bring 26,000 items a year back in house?
- ‘De-risking’ by bringing services in-house versus optimising procurement pathways and service design

Summary

- Continued trend towards immunotherapy, especially with long-term maintenance
- NHS Ten Year Plan: Shift from hospital to community care
- Renewed focus on homecare and patient experience
- Subcutaneous administration with key molecules potentially presents opportunities to release capacity
- Biosimilar medicines remain significant way to deliver medicines value targets but consider costs beyond drug alone

Impact on Aseptic Production

- Cost saving opportunities change over time
- Better to make a smaller selection of high-volume products or retain flexibility with a larger catalogue?
- How does your unit support your clinical service?
- Injectable risk assessments

Resources

- Specialist Pharmacy Service (SPS)
  - Understanding biosimilar and generic market entry
  - Prescribing Outlook
  - Biosimilar and key generic medicines webinars
- NHS Futures Platform
  - Commissioning updates

Thanks for listening

Questions?