

Dose Banded Chemotherapy Standardised Product Specifications User Guide

National Standard Chemotherapy Product Specifications

Each dose banded chemotherapy drug has an individual standardised product specification. However, these must be read in conjunction with the separate but over-arching General Product Specification Requirements document that applies to all the standardised product specifications.

These standardised specifications should now be used by NHS Trusts in England when outsourcing the supply of dose banded chemotherapy products, and during any tendering process. Where an individual product specification doesn't yet exist, the principles set out in the General Product Specification Requirements document should be used until the individual specification becomes available.

NHS Trusts should as far as possible adopt the specifications for dose banded chemotherapy drugs compounded internally. It is accepted however that due to variations in the different ePrescribing systems used in England this may not be absolutely possible. Nevertheless the principles contained within the specifications should be applied as widely as they can, and where a local limitation is identified a documented gap analysis should be performed with a clear outline of what actions have been taken to resolve the issue (e.g. inclusion on System Supplier's future enhancement requests) and any mitigation that has been put in place to minimise any identified clinical risks.

Information for Purchasers and Suppliers of Outsourced Products

The national standardised product specifications for dose banded chemotherapy drugs are intended to provide the minimum NHS England requirements for product presentations and are not an absolute product specification in every respect i.e. suppliers will need to include within their own individual product specifications the assigned shelf life, stability references, starting material suppliers, MIA numbers etc., which will be needed for tender assessments when tendering for contracts as required by CMU and Regional contracting processes.

The standards and principles contained within this <u>guidance document</u> should be used by both NHS Trusts purchasing, and Suppliers supplying dose banded chemotherapy products as unlicensed medicines.

Target Group for Standardised Chemotherapy Products

The national standardised product specifications for dose banded chemotherapy drugs are intended for adult chemotherapy services within NHS England. However, paediatric services may adopt them where appropriate e.g. for teenagers, if they wish to.

January 2018