General Product Specification Requirements

Component Materials

Maximum fill volume in syringes (NHS PASG Guidelines):-

Syringe size (ml)	Max fill volume (ml)	Measurable graduations
1	0.85	0.01ml
3	2.5	0.1ml
5	4	0.2ml
10	8	0.2ml
20	17	1ml
30	25	1ml
50 (60ml nominal)	50	1ml

It is permissible for suppliers to apply their own (lower) maximum fill volumes where they have tighter integrity test limits. However, the maximum fill volumes stated here must not be exceeded.

All individual containers (syringes, infusion bags and elastomeric devices) shall be labelled with:
- the approved name of the drug (& brand name for biologicals) and, where relevant, the name of the diluents or carrier fluid
- the total dose in the container of drug stated in the specified volume using the metric system only. Where the dose is expressed in micrograms then this shall be written in full. Abbreviating to mcg is not acceptable.
- the intended route of administration, using approved abbreviations only, as detailed in NPSA & MHRA guidance.
- the required storage conditions, which shall be stated as 'Store in a Refrigerator at 2-8^{o}C' or 'Store at Room Temperature' as appropriate. 'Protect From Light' shall be included on the label unless it can be demonstrated that the product is not affected by exposure to light.
- the batch number and expiry date & time (where relevant)
- the name and MS number of the manufacturer
- warnings, including 'Cytotoxic' & standard NPSA Vinca Alkaloid wording where relevant. 'Keep out of the reach and sight of children' shall be stated.
- 'Check the solution is free from particles before administering' should be added for products known to be at risk of precipitation during storage & within the shelf life of the product. N.B. It is expected that all products will be free from particulates (bung, plastic fragments etc.) at the time of release as part of the normal inspection processes.

The design of the label and its placement on the product should enable critical information to be read easily in one field of view and enable similar products to be easily distinguished. This is especially important where the syringe size in comparison to the label size requires the label to be attached as a 'flag' if a smaller label can't be used. In this case the label must be flat without the need to turn it over to be read. Consideration should be given as to whether placement of the 'flag' will hinder administration of the drug. Labels applied to syringes should be placed so as not to obscure graduation marks or the plunger tip. Labels applied to infusion bags should be placed so as not to obsucure the name of the infusion solution. Labels applied to elastomeric devices should be placed so as not to obscure the name or the infusion rate of the device.

To aid product differentiation Tall Man lettering should be used as appropriate for the drug name on product labels using the format in each standard product specification. Colour may be used to distinguish/highlight critical information included on the labels, but colour coding schemes must not be used.

Labels should include a machine readable bar code, preferably one which conforms to the GS1 coding system (www.gs1uk.org) and in compliance with PEPPOL requirements (http://www.peppol.eu).

Pre-filled syringe presentations:- the syringe provided must be polypropylene or polycarbonate, luer lock, graduated in millilitres and closed with a suitable blind hub/syringe cap. Air bubbles within the product must be minimised so that the end-user can use the product without needing to remove air.

Infusion bag presentations:- the bag must be flexible and latex free. Non-PVC bags should be used. Infusion bags must be supplied with the additive port secured by a suitable additive cap. Drug additions should be made to a bag without removing the corresponding volume of drug added and the product label shall reflect this by stating the nominal bag volume plus addition volume. Where it is necessary to remove some volume from the bag in order to add the total dose, the label shall state the nominal bag volume plus the net addition volume. N.B. The bag overage should not be included within the volume stated on the label. Wording stating 'Infuse the entire contents of the bag' should be included on the label. The bag volume should be stated in whole mls on the label i.e. no decimals. This is in addition to the general labelling requirements above.

Elastomeric device presentations:- the device must be latex free. The filling port must be secured with a suitable cap, and the patient administration line must have a luer lock connector secured with a suitable cap. The patient administration line should be primed so that air is removed from the line in order that the end user can use the product without needing to do so. Where an in-line filter is incorporated into the administration line, then priming should only be to the filter and not beyond with a clamp in place & closed before the filter i.e. between the reservoir and filter. An overage volume should not be added to the device to account for any dead space, as this is not critical for chemotherapy. In addition to the general labelling requirements above, the label must state the total dose and total volume in the device and include the device infusion rate stated in ml/hr. The device volume should be stated in whole mls on the label i.e. no decimals. Wording stating 'Infuse the entire contents of the device' should be included on the label.

Outer packaging

Items must be packed in a way that does not put the person unpacking products at risk from exposure to cytotoxic products i.e.
- adequate labelling on the outer packaging to highlight that the contents are cytotoxic
- packaging the products in such a way to give them adequate protection from damage during transit
- any other reasonable precaution

Each product (dose) will be individually labelled. Each labelled product will be sealed in a leak-proof wrap.
If the label on the product cannot be read through the leak-proof wrap e.g. if the wrap used is light protective, a label identical to the product label will be applied to the wrap. It is acceptable for product requiring light protection to be sealed in transparent leak-proof wrap. However each product (dose) will be supplied with a light protective cover.

If product is supplied in 'multiples' the individually labelled/wrapped product will be sealed in outer packaging containing no more than 10 products (doses).

The outer wrap (multipacks) will be labelled with the contents including quantities, batch number, expiry and storage conditions.

CQUIN 1 Drugs

The drugs included in this specification are: -

Bendamustine
Bortezomib Subcut
Carboplatin
Cisplatin
Cyclophosphamide (syringes & bags)
Docetaxel
Doxorubicin
Epirubicin
Fluorouracil (syringes, bags & elastomeric devices)
Gemcitabine
Irinotecan
Oxaliplatin
Paclitaxel
Pemetrexed
Rituximab IV Infusion
Vinblastine
Vincristine

National Dose Banding Tables

The national chemotherapy dose banding tables have been published on the NHS England website:
https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-b/b02/