Dose Banded Chemotherapy Standardised Products

Appendix 2

Agreed Changes Made to the Standard Product Specifications by the Expert Group Following Review of the Stakeholder Testing Responses

1) **General consultation comments analysis**
   a) Agreed where doses are expressed in micrograms then specify on labels as micrograms in full, or where other doses for the drug are normally expressed in whole mg then e.g. 0.1mg may be acceptable. Abbreviating to mcg is not acceptable. **Clarified in the general specification requirements**
   b) Agreed labels do need to state address/identifier of the supplier & keep out of reach of children (full wording). Manufacturer details are listed on individual product label requirements & in the general specification requirements, but keep out of the reach of children is only on the individual product labels. **Keep out of the reach and sight of children wording added to the general specification requirements**
   c) Agreed to state requirement for particle free only applies where products prone to precipitation e.g. Paclitaxel, Docetaxel, 5FU 50mg/ml, Gemcitabine etc. **Added to appropriate product specification labels and clarification added to the general specification requirements**
   d) Light protective packaging is covered in general specification requirements, but agreed to move 'Outer packaging' section in the general specification requirements to be above the list of drugs to improve prominence. **General specification requirements re-ordered accordingly**
   e) Disagreed with a single response that 'dose limits should not be stated as dependent on available stability data (local & from suppliers)' as there is a need to link product specification doses to the national dose banding table doses and have a single NHS standard for each product. **No change required**
   f) Agreed that it is not feasible to specify a single NHS defined label format at this time due to different ePrescribing & labelling systems in place, especially in unlicensed NHS units. **No change required currently**
   g) Syringe maximum fill volumes set at 85% (PASG/PQA) – Suppliers may have tighter limits from their own integrity testing. Agreed the need to clarify that these are maximum limits and lower fill volumes are accecptable. However, the maximum fill volume specified must not be exceeded. **Clarified in the general specification requirements**
   h) Agreed the need to clarify in supporting information published alongside the national product specifications that they are intended to provide the minimum NHS 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 contratcts as required by CMU and Regional contracting processes. Also, there is a need to specify in the supporting information that the specifications are intended for

adult chemotherapy only. However, paediatric services may adopt them where appropriate e.g. for teenagers, if they wish to. **Clarification to be included within a supporting document to be published alongside the product specifications**

i) Agreed the need to specify that labels on syringes should be placed so as not to obscure graduation marks and also the plunger tip. Where syringe size in comparison to the label size means labels need to be attached as a 'flag', then this should be flat so that all the information can easily be read in one view without the need to turn the label over. Labels applied to infusion bags should not obscure the name of the infusion solution, and on elastomeric devices the infusion rate of the device. **Added to the general specification requirements**

j) Agreed storage requirements on labels should be expressed as follows:- Store in a Refrigerator at 2 to 8^{o}C or Store at Room Temperature. **Labels updated within individual product specifications accordingly, and included in the general specifcation requirements**

2) Infusion bag labelling consultation analysis

Agreed to add wording to infusion bag labelling option A (nominal bag volume plus addition volume) stating 'infuse the entire contents of the bag'. This should also satisfy those whose first choice preference was for either option B or C and thereby achieve greater consensus. **Labels updated within individual product specifications accordingly, and included in the general specifcation requirements. N.B. Similar wording also added to device specifications 'infuse the entire contents of the device' for a consistent approach.**

3) Tall Man lettering consultation analysis

Agreed to update Tall Man lettering as per the FDA/ISMP document www.ismp.org/Tools/tallmanletters.pdf (where drugs listed) or otherwise in accordance with email correspondence with Dr. David Gerrett, Senior Pharmacist Patient Safety, NHS Improvement (on file). Also agreed that Fluorouracil should not be in this format as advised by Dr. Gerrett. Agreed that wording about the use of colour was appropriate within the general specification requirements. **Tall man lettering updated as agreed on the labels within each individual product specification**

4) 5FU strengths for elastomeric devices consultation analysis

Agreed to include both strengths in the specification. **The product specification has been updated accordingly**

5) Cisplatin bag volumes consultation analysis

a) Agreed to include both bag sizes in the spec. **The product specification has been updated accordingly**

b) Agreed to allow other bag sizes as well where concentration dependent stability is used by suppliers for their stability. **Included within the product specification** However agreed not to include dose ranges for each bag size in the product specification as hydration regimens have not been standardised nationally. **No change required**

c) Agreed there was no need to include a specification containing potassium with Cisplatin as potassium can be included elsewhere within hydration regimens. **No change required**

6) Other questions/points raised during the consultation

a) Agreed to include protect from light on syringe labels as well as infusions. **Individual syringe product specifications updated accordingly**

b) Agreed that polycarbonate as well as polypropylene syringes should be included. **Individual syringe product specifications updated accordingly, and included in the general specifcation requirements**

c) Agreed that the product specification for Paclitaxel should remain as is for the infusion fluid (saline) and storage requirements (Room Temperature) as the NHS standard for this product. Some supplier specifications include glucose or refrigerated storage for their products. This would lead to too many variations, and one NHS standard is required. **No change required**

d) Elastomeric devices – agreed to update the general specification requirement to prime the line to the in-line air filter where incorporated with the device. **General specification requirements updated accordingly**

e) Elastomeric devices – agreed that not including any volume overage for 'dead space' in devices was not critical for chemotherapy. **General specification requirements updated accordingly**

f) Elastomeric devices – agreed to amend the general specification requirements to specify the rate of the device in m/hr on the label rather than 'infuse over xxdays or hours', as this was agreed as a better suggestion and more likely to be in accordance with the prescription. **Individual device product specification label updated accordingly, and included in the general specifcation requirements**

However, disagreed that the device name should be included on the label as less likely to be stated on the prescription. **No change required**