Document No. 04b

Project Title: NHS Framework Agreement for Branded Medicines - National Tender - 1 May 2024

Offer reference number: CM/PHR/22/5682

CM/PHR/22/5682/01 - NHS Framework Agreement for Branded Medicines - National Tender - Lot 1. Period of framework: 1 May 2024 to 30 April 2028.

CM/PHR/22/5682/02 - NHS Framework Agreement for Branded Medicines - National Tender - Lot 2. Period of framework: 1 May 2024 to 30 April 2025 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 24 months.

Assessment Criteria, Stability Protocol and Additional Specification Requirements

Assessment criteria

1. All medicines must conform to the fixed gateway criteria listed in Document No. 07b – Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines v6 (October 2023), Appendix 1. Non-compliance on any single point will result in a Critical Score (refer to 3.3 Document No. 07b).

   Medicine packaging should comply to best practice for labelling and packaging to ensure that medicines can be used safely by all patients, the public and healthcare professionals alike. Good practice principles set out in:

   - Best practice guidance on the labelling and packaging of medicines (MHRA December 2020)
   - Promoting safer use of injectable medicines (NPSA Alert 20, March 2007)
   - Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008)
   - Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA 2008) ISBN: 978-1-906624-02-6

   If unacceptable patient safety risks are identified for which risk mitigation measures are likely to be impracticable or insufficiently effective a critical score will be assigned to the medicine.

2. Please find below a link to the Stability Protocol:

Stability-part-1-small-molecules-5th-Ed-Sep

APPENDIX A

Additional Specification Requirements (supplementary to general and regulatory)

The NHS has additional requirements to those identified within the general specification. Those requirements are specified within this Appendix A to Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements.

Awards for these products will be made, where possible, to offers meeting the additional specification (subject to the offers meeting all other contract award criteria stated in paragraph 11.1 of Document No. 02 – Terms of Offer).
Offers for products that do not meet the additional specification will only be awarded to the framework agreement in the absence of any offers meeting the additional specification (subject to the offers meeting all other award criteria stated in paragraph 11.1 of Document No. 02 – Terms of Offer).

Offerors product information within PharmaQC will be used to determine whether offered products meet the addition requirements where possible. The Product details and pack details recorded (not artwork or photographs) will be used and, in the absence of the relevant fields being completed, it will be deemed that the offered product does not meet the requirement.

1. Packaging protection from light

The NHS requires the following products to be contained in packaging designed to protect the product from light:

N/A

2. Cytotoxic products in blister packs/sachets or with Child Resistant Closure (CRC)

The NHS requires the following cytotoxic products to be contained in a blister pack (or sachet) presentation or have a CRC if the presentation is in a bottle/tub:

NPC	Description
DHA002	BUSULFAN TABLETS 2MG
DHA008	CHLORAMBUCIL TABLETS 2MG
DHD001	ETOPOSIDE CAPSULES 100MG
DHD002	ETOPOSIDE CAPSULES 50MG
DHB013	IDARUBICIN CAPSULES 10MG
DHB017	IDARUBICIN CAPSULES 5MG
DQK067	IDELALISIB FILM COATED TABLETS 100MG

NPC	Description
DQK066	IDELALISIB FILM COATED TABLETS 150MG
DHC024	TOPOTECAN CAPSULE 250MCG
DHB016	TOPOTECAN CAPSULES 1MG
DHA045	TREOSULFAN CAPSULES 250MG

As stated in Document No. 04a Quality Assurance Process, Table 1, a SPC will be required as part of the tender submission on Pharma QC to ensure products are compliant with the presentation requirements stated above.

3. Specific administration requirements

The NHS requires the following product to be licensed for administration both with and without dilution:

N/A

The NHS requires the following product to be licensed for the route(s) of administration to include intrathecal route:

N/A

The NHS requires the following product to be licensed for the route(s) of administration to include Intramuscular and Intravenous:

N/A

4. Oral liquid products to have Child Resistant Closure (CRC)

The NHS requires the following oral liquid products to have a CRC:

N/A

Where no offered product includes a CRC the product should be such that the end-user should be able to apply one if required.

As stated in Document No. 04a Quality Assurance Process, Table 1, a SPC will be required as part of the tender submission on Pharma QC to ensure products are compliant with the presentation requirements stated above.

5. Patient Packs

Where offers are received for tablets or capsules or oral solutions/suspensions which do not represent the tendered pack size but represent a suitable alternative patient pack for dispensing awards will be made to the lowest-priced offered patient pack (subject to the offers meeting all other award criteria stated in criteria stated in paragraph 11.1 of Document No. 02 – Terms of Offer).

6. Additional Specification Requirements

- Sugar free to be defined as being free from fructose, glucose, or sucrose. (see Guidance on prescribing | Medicines guidance | BNFC | NICE)
- The NPC descriptor 'form' may indicate any of the following terms: suspension, oral solution, syrup or elixir. Regardless of the term used, as long as the product is in an oral liquid formulation, it shall be considered acceptable.
- Perindopril - For perindopril erbumine, any products labelled as 'Perindopril Tert-Butylamine' are acceptable. Erbumine and tert-butylamine are equivalent and used interchangeably.

7. Products with labels applied over any original packaging

The following products are those which are used in an aseptic setting and will receive a 'Critical' QA score if the product offered is supplied as re-boxed with an overlabelled primary container, or entirely over-labelled with a label in English that obscures or partly obscures the original text in another language.

NPC	Description
DHA380	CETUXIMAB SOLUTION FOR INJECTION VIAL 100MG/20ML
DHA381	CETUXIMAB SOLUTION FOR INJECTION VIAL 500MG/100ML
DHA117	CRISANTASPASE (ERWINIA) POWDER FOR SOLUTION FOR INJECTION VIAL 10000UNIT
DHA272	CRISANTASPASE (ERWINIA) POWDER FOR SOLUTION FOR INJECTION VIAL 10000UNIT
DHA152	DACTINOMYCIN INJECTION 500MG
DHA269	DOXORUBICIN (LIPOSOMAL) PWDR AND SOLV FOR SUSP FOR INJ VIAL 50MG
DHB110	GEMTUZUMAB OZOGMACIN INJECTION 5MG
DBQ017	IDARUCIZUMAB SOLUTION FOR INFUSION VIAL 2.5G/50ML
DXA012	IPILIMUMAB SOLUTION FOR INJECTION VIAL 200MG/40ML
DXA011	IPILIMUMAB SOLUTION FOR INJECTION VIAL 50MG/10ML
DHK033	OFATUMUMAB SOLUTION FOR INFUSION VIALS 100MG/5ML
DHK034	OFATUMUMAB SOLUTION FOR INFUSION VIALS 1G/5ML
DEC158	PALIVIZUMAB PWD AND SOLV FOR SOL 100MG VIAL
DEC164	PALIVIZUMAB PWD AND SOLV FOR SOL 50MG VIAL
DEC145	PALIVIZUMAB SOLUTION FOR INJECTION VIALS 100MG/1ML
DEC148	PALIVIZUMAB SOLUTION FOR INJECTION VIALS 50MG/0.5ML
DHB157	PANITUMUMAB SOLUTION FOR INFUSION VIAL 100MG/5ML
DHC022	PANITUMUMAB SOLUTION FOR INFUSION VIAL 400MG/20ML
DHA369	PEGASPARAGINASE INJECTION 3750 UNITS IN 5ML
DHA249	RALTITREXED POWDER FOR SOLUTION INJ 2MG VIAL
DAC050	RAMUCIRUMAB SOLUTION FOR INFUSION VIALS 100MG/10ML
DAC058	RAMUCIRUMAB SOLUTION FOR INFUSION VIALS 500MG/50ML
DND056	SILTUXIMAB 100MG POWDER FOR SOLUTION FOR INFUSION VIALS
DHK056	SILTUXIMAB 400MG POWDER FOR SOLUTION FOR INFUSION VIALS
DHA395	TRABECTEDIN POWDER FOR SOL FOR INJ VIAL 1MG
DHA394	TRABECTEDIN POWDER FOR SOL FOR INJ VIAL 250MCG