Document No. 04b

Project Title: NHS Branded Medicines Framework for North of England and Midlands and East - 1 March 2024

Offer reference number: CM/PHR/22/5678

CM/PHR/22/5678/01 - NHS Framework for NORTH OF ENGLAND Branded Medicines - Tranche B. Period of framework: 1 March 2024 to 31 August 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.

CM/PHR/22/5678/02 - NHS Framework for NORTH OF ENGLAND Branded Medicines (to transition to Tranche B) Period of framework: 1 March 2024 to 31 August 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.

CM/PHR/22/5678/03 - NHS Framework for MIDLANDS AND EAST of England Branded Medicines - Tranche A. Period of framework: 1 March 2024 to 31 August 2026 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 12 months.

CM/PHR/22/5678/04 - NHS Framework for MIDLANDS AND EAST of England Branded Medicines (to transition to Tranche B). Period of framework: 1 March 2024 to 31 August 2025 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 12 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:

N/A

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.

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
DHB123	ALEMTUZUMAB SOLUTION FOR INFUSION VIAL 12MG/1.2ML
DKE069	INFLIXIMAB (FLIXABI) SOLUTION FOR INFUSION VIAL 100MG
DHF010	INFLIXIMAB (INFLECTRA OR EQ) SOLUTION FOR INFUSION VIAL 100MG
DAE056	INFLIXIMAB (REMICADE OR EQ) SOLUTION FOR INFUSION VIAL 100MG
DHF011	INFLIXIMAB (REMSIMA OR EQ) SOLUTION FOR INFUSION VIAL 100MG
DEI088	INFLIXIMAB (ZESSLY) SOLUTION FOR INFUSION VIALS 100MG
DHB087	RITUXIMAB (MABTHERA) SOLUTION FOR INFUSION VIAL 100MG/10ML
DHB083	RITUXIMAB (MABTHERA) SOLUTION FOR INFUSION VIAL 500MG/50ML
DHC110	RITUXIMAB (RIXATHON) SOLUTION FOR INFUSION VIAL 100MG/10ML
DHC113	RITUXIMAB (RIXATHON) SOLUTION FOR INFUSION VIAL 500MG/50ML
DHC114	RITUXIMAB (RIXATHON) SOLUTION FOR INFUSION VIAL 500MG/50ML
DHC238	RITUXIMAB (RUXIENCE) SOLUTION FOR INFUSION VIAL 100MG/10ML
DHC239	RITUXIMAB (RUXIENCE) SOLUTION FOR INFUSION VIAL 500MG/50ML
DHC111	RITUXIMAB (TRUXIMA) SOLUTION FOR INFUSION VIAL 100MG/10ML
DHC112	RITUXIMAB (TRUXIMA) SOLUTION FOR INFUSION VIAL 500MG/50ML
DHB127	RITUXIMAB SOLUTION FOR INJECTION VIAL 1400MG/11.7ML
DKE072	BELIMUMAB POWDER FOR SOLUTION FOR INFUSION VIALS 120MG
DKE073	BELIMUMAB POWDER FOR SOLUTION FOR INFUSION VIALS 400MG
DHA477	BEVACIZUMAB (ALYMSYS) SOLUTION FOR INJECTION VIAL 100MG/4ML
DHA478	BEVACIZUMAB (ALYMSYS) SOLUTION FOR INJECTION VIAL 400MG/16ML
DHA357	BEVACIZUMAB (AVASTIN) SOLUTION FOR INJECTION VIAL 100MG/4ML
DHA358	BEVACIZUMAB (AVASTIN) SOLUTION FOR INJECTION VIAL 400MG/16ML
DHA469	BEVACIZUMAB (AYBINTIO) SOLUTION FOR INJECTION VIAL 100MG/4ML
DHA470	BEVACIZUMAB (AYBINTIO) SOLUTION FOR INJECTION VIAL 400MG/16ML
DHA476	BEVACIZUMAB (OYAVAS) SOLUTION FOR INJECTION VIAL 100MG/4ML
DHA475	BEVACIZUMAB (OYAVAS) SOLUTION FOR INJECTION VIAL 400MG/16ML
DLH014	BEVACIZUMAB (VEGZELMA) SOLUTION FOR INJECTION VIAL 100MG/4ML
DLH015	BEVACIZUMAB (VEGZELMA) SOLUTION FOR INJECTION VIAL 400MG/16ML
DLH030	BEVACIZUMAB (VERSAVO) SOLUTION FOR INJECTION VIAL 100MG/4ML
DLH031	BEVACIZUMAB (VERSAVO) SOLUTION FOR INJECTION VIAL 400MG/16ML
DHA471	BEVACIZUMAB (ZIRABEV) SOLUTION FOR INJECTION VIAL 100MG/4ML
DHA472	BEVACIZUMAB (ZIRABEV) SOLUTION FOR INJECTION VIAL 400MG/16ML
DCD099	MEPOLIZUMAB (NUCALA) POWDER FOR SOLUTION FOR INJECTION VIAL 100MG
DCD086	OMALIZUMAB PDR AND SOLV FOR SOL FOR INJ VIAL 150MG
DHB268	RESLIZUMAB (CINQAERO) SOLUTION FOR INFUSION VIALS 100MG/10ML
DHB269	RESLIZUMAB (CINQAERO) SOLUTION FOR INFUSION VIALS 25MG/2.5ML
DLA039	RISANKIZUMAB SOLUTION FOR INFUSION VIALS 600MG/10ML
DIA525	SECUKINUMAB (COSENTYX) POWDER FOR SOLUTION FOR INJECTION 150MG

DHC041	TRASTUZUMAB (HERCEPTIN) POWDER FOR SOLUTION FOR INFUSION VIAL 150MG
DXA053	TRASTUZUMAB (HERCEPTIN) SOLUTION FOR INJECTION VIAL 600MG/5ML
DLK026	TRASTUZUMAB (HERZUMA) POWDER FOR SOLUTION FOR INFUSION VIAL 150MG
DLK031	TRASTUZUMAB (HERZUMA) POWDER FOR SOLUTION FOR INFUSION VIAL 420MG
DLK024	TRASTUZUMAB (KANJINTI) POWDER FOR SOLUTION FOR INFUSION VIAL 150MG
DLK023	TRASTUZUMAB (KANJINTI) POWDER FOR SOLUTION FOR INFUSION VIAL 420MG
DLK025	TRASTUZUMAB (ONTRUZANT) POWDER FOR SOLUTION FOR INFUSION VIAL 150MG
DLK030	TRASTUZUMAB (TRAZIMERA) POWDER FOR SOLUTION FOR INFUSION VIAL 150MG
DLK035	TRASTUZUMAB (TRAZIMERA) POWDER FOR SOLUTION FOR INFUSION VIAL 420MG
DHC240	TRASTUZUMAB (ZERCEPAC) POWDER FOR SOLUTION FOR INFUSION VIAL 150MG
DBP037	TRASTUZUMAB (ZERCEPAC) POWDER FOR SOLUTION FOR INFUSION VIAL 420MG
DBP036	TRASTUZUMAB (ZERCEPAC) POWDER FOR SOLUTION FOR INFUSION VIAL 60MG
DLH017	TRASTUZUMAB DERUXTECAN (ENHERTU) POWDER FOR SOLUTION FOR INFUSION VIAL 100MG
DHB250	USTEKINUMAB INJECTION FOR INTRAVENOUS INFUSION VIAL 130MG
DIA007	USTEKINUMAB SOLUTION FOR INJECTION VIAL 45MG/0.5ML
DAL017	VEDOLIZUMAB POWDER FOR SOLUTION FOR INFUSION VIALS 300MG