**Document No. 04b**

**Project title: NHS National Generic Pharmaceuticals Wave 15a**

**Offer reference number: CM/PHG/23/5697**

**Period of framework agreement:** Dates detailed below, with an option or options to extend (at the authority’s discretion) for a period or periods up to a total of 48 months.

**Potential periods of call-offs under the framework agreement:**

**CM/PHG/23/5697/01 - Orals (plus non-parenteral) Products:**

All Regions (CESW/LSNE/NWLN): 01/02/2025 to 31/05/2027 (28 months)

**CM/PHG/23/5697/02 - Hospital Only Products:**

DNW & DLN: 01/02/2025 to 31/01/2027 (24 months)

**CM/PHG/23/5697/03 - Hospital Only Products (Housekeeping):**

DLS & DNE: 01/02/2025 to 31/05/2026 (16 months)

DCE & DSW: 01/02/2025 to 30/09/2025 (8 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.

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



**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 award criteria stated in paragraph 12.1.5 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 12.1.5 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 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:

Ciprofloxacin solution for infusion 200mg/100ml

Ciprofloxacin solution for infusion 400mg/200ml

1. **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:

Cyclophosphamide Tablets 50mg

Imatinib Tablets/Capsules 100mg

Imatinib Tablets/Capsules 400mg

Temozolomide Capsules 100mg

Temozolomide Capsules 140mg

Temozolomide Capsules 180mg

Temozolomide Capsules 250mg

Temozolomide Capsules 5mg

Temozolomide Capsules 20mg

Capecitabine Tablets 150mg

Capecitabine Tablets 300mg

Capecitabine Tablets 500mg

Vinorelbine Capsules 20mg

Vinorelbine Capsules 30mg

Vinorelbine Capsules 80mg

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.

1. **Specific administration requirements**

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

Phenytoin Sodium Solution for Injection Ampoule 250mg/5ml

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

Methotrexate Solution for Injection Vial 50mg/2ml (For IV, IM and Intrathecal Use)

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

Ondansetron Solution for Injection Ampoule (For IV and IM Use) 4mg/2ml

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

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

|  |
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| ACTIVATED CHARCOAL ORAL SUSPENSION SUGAR FREE 200MG/ML (250ML) |
| ATOVAQUONE ORAL SUSPENSION SUGAR FREE 750MG/5ML (226ML) |
| CEFACLOR ORAL SUSPENSION 125MG/5ML (100ML) |
| CEFACLOR ORAL SUSPENSION 250MG/5ML (100ML) |
| CEFALEXIN ORAL SUSPENSION 125MG/5ML (100ML) |
| CEFALEXIN ORAL SUSPENSION 250MG/5ML (100ML) |
| CHLORAL HYDRATE ORAL SOLUTION 500MG/5ML 150ML |
| CHLORPROMAZINE ORAL SOLUTION SUGAR FREE 25MG/5ML (150ML) |
| CO-AMOXICLAV ORAL SUSPENSION 400MG/57MG/5ML (70ML) |
| CO-DANTHRAMER ORAL SUSPENSION SUGAR FREE 25MG/200MG/5ML (300ML) |
| CO-DANTHRAMER ORAL SUSPENSION SUGAR FREE 75MG/1000MG/5ML (300ML) |
| CODEINE PHOSPHATE LINCTUS SUGAR FREE 15MG/5ML (200ML) |
| DIAZEPAM ORAL SOLUTION SUGAR FREE 2MG/5ML (100ML) |
| FERROUS FUMARATE ORAL SOLUTION SUGAR FREE 140MG IN 5ML (300ML) |
| HALOPERIDOL ORAL SOLUTION SUGAR FREE 10MG/5ML (100ML) |
| MACROGOL 3350 ORAL LIQUID NPF SUGAR FREE 13.9G/25ML 500ML |
| NITISINONE ORAL SUSPENSION (SUGAR FREE) 4MG/1ML (90ML) |
| OSELTAMIVIR ORAL SUSPENSION (SUGAR FREE) 30MG/5ML (65ML) |
| PARACETAMOL ORAL SUSPENSION 250MG/5ML 100ML |
| PARACETAMOL ORAL SUSPENSION 250MG/5ML 500ML |
| PARACETAMOL ORAL SUSPENSION PAEDIATRIC SUGAR FREE 120MG/5ML 100ML |
| PARACETAMOL ORAL SUSPENSION SUGAR FREE 250MG/5ML 100ML |
| PARACETAMOL ORAL SUSPENSION SUGAR FREE 250MG/5ML 200ML |
| PARACETAMOL ORAL SUSPENSION SUGAR FREE 250MG/5ML 500ML |
| POSACONAZOLE ORAL SUSPENSION 40MG/ML (105ML) |
| RIFAMPICIN ORAL SUSPENSION 100MG/5ML (120ML) |
| SODIUM CITRATE ORAL SOLUTION 441.17MG/5ML (0.3M) (30ML) |
| SODIUM OXYBATE ORAL SOLUTION (SUGAR FREE) 500MG/ML (180ML) |
| SODIUM PICOSULFATE ORAL SOLUTION (SUGAR FREE) 5MG/5ML (100ML) |
| SODIUM PICOSULFATE ORAL SOLUTION (SUGAR FREE) 5MG/5ML 300ML |

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.

1. **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 12.1.5 of Document No. 02 – Terms of Offer).

1. **Additional Specification Requirements**

* Sugar free to be defined as being free from fructose, glucose, or sucrose. (see [Guidance on prescribing | Medicines guidance | BNFC | NICE](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fbnfc.nice.org.uk%2Fmedicines-guidance%2Fguidance-on-prescribing%2F%23%3A~%3Atext%3DExcipients%2Cdo%2520not%2520cause%2520dental%2520caries.&data=05%7C01%7Crachel.williams11%40nhs.net%7C95aa312329ef471b32c508dbc4b54c8b%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638320055173369253%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=bW7%2BS0VHjJEvxiCvLIdLg%2BBVFSujQMGTxO5rZp4W170%3D&reserved=0))
* 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.

1. **Products with labels applied over primary packaging which are used in an aseptic setting**

The NHS requires the primary container of the following products which are used in an aseptic setting to bear an original label in English (i.e. NOT overlabelled).

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| ARSENIC TRIOXIDE SOLUTION FOR INFUSION 10MG/10ML |
| ARSENIC TRIOXIDE SOLUTION FOR INFUSION 20MG/20ML |
| ARSENIC TRIOXIDE SOLUTION FOR INFUSION VIAL 12MG/6ML |
| AZACITIDINE POWDER FOR SUSPENSION FOR INJECTION VIAL 100MG |
| AZACITIDINE POWDER FOR SUSPENSION FOR INJECTION VIAL 150MG |
| BENDAMUSTINE HYDROCHLORIDE CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 180MG/4ML |
| BENDAMUSTINE HYDROCHLORIDE POWDER FOR SOLUTION FOR INFUSION VIAL 100MG |
| BENDAMUSTINE HYDROCHLORIDE POWDER FOR SOLUTION FOR INFUSION VIAL 25MG |
| BLEOMYCIN POWDER FOR SOLUTION FOR INJECTION VIAL 15 000 UNITS |
| BORTEZOMIB POWDER FOR SOLUTION FOR INJECTION VIAL 2.5MG |
| BORTEZOMIB POWDER FOR SOLUTION FOR INJECTION VIAL 3.5MG |
| BORTEZOMIB SOLUTION FOR INJECTION VIAL 3.5MG/1.4ML |
| BUSULFAN SOLUTION FOR INFUSION VIAL 60MG/10ML |
| CABAZITAXEL CONCENTRATE AND SOLVENT FOR SOLUTION FOR INFUSION 60MG/1.5ML VIAL |
| CABAZITAXEL CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 45MG/4.5ML |
| CABAZITAXEL CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 50MG/5ML |
| CABAZITAXEL CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 60MG/3ML |
| CABAZITAXEL CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 60MG/6ML |
| CARBOPLATIN SOLUTION FOR INFUSION VIAL 150MG/15ML |
| CARBOPLATIN SOLUTION FOR INFUSION VIAL 450MG/45ML |
| CARBOPLATIN SOLUTION FOR INFUSION VIAL 50MG/5ML |
| CARBOPLATIN SOLUTION FOR INFUSION VIAL 600MG/60ML |
| CARMUSTINE PDR & SOLV FOR SOL FOR INJ VIAL 100MG |
| CISPLATIN SOLUTION FOR INFUSION VIAL 100MG/100ML |
| CISPLATIN SOLUTION FOR INFUSION VIAL 10MG/10ML |
| CISPLATIN SOLUTION FOR INFUSION VIAL 50MG/50ML |
| CYCLOPHOSPHAMIDE POWDER FOR SOLUTION FOR INJECTION VIAL 1G |
| CYCLOPHOSPHAMIDE POWDER FOR SOLUTION FOR INJECTION VIAL 2G |
| CYCLOPHOSPHAMIDE POWDER FOR SOLUTION FOR INJECTION VIAL 500MG |
| CYTARABINE SOLUTION FOR INJECTION VIAL 100MG/1ML |
| CYTARABINE SOLUTION FOR INJECTION VIAL 100MG/5ML (FOR IV, SC, AND INTRATHECAL USE) |
| CYTARABINE SOLUTION FOR INJECTION VIAL 1G/10ML |
| CYTARABINE SOLUTION FOR INJECTION VIAL 2G/20ML |
| CYTARABINE SOLUTION FOR INJECTION VIAL 500MG/5ML |
| DACARBAZINE POWDER FOR SOLUTION FOR INFUSION VIAL 1000MG |
| DACARBAZINE POWDER FOR SOLUTION FOR INFUSION VIAL 500MG |
| DACARBAZINE POWDER FOR SOLUTION FOR INJECTION VIAL 100MG |
| DACARBAZINE POWDER FOR SOLUTION FOR INJECTION VIAL 200MG |
| DOCETAXEL SOLUTION FOR INFUSION VIAL 160MG/8ML (20MG/ML) |
| DOCETAXEL SOLUTION FOR INFUSION VIAL 20MG/1ML (20MG/ML) |
| DOCETAXEL SOLUTION FOR INFUSION VIAL 80MG/4ML (20MG/ML) |
| DOXORUBICIN HYDROCHLORIDE PEGYLATED LIPOSOMAL SOLUTION FOR INFUSION VIAL 20MG/10ML |
| DOXORUBICIN HYDROCHLORIDE PEGYLATED LIPOSOMAL SOLUTION FOR INFUSION VIAL 50MG/25ML |
| DOXORUBICIN HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 200MG/100ML |
| DOXORUBICIN HYDROCHLORIDE SOLUTION FOR INJECTION VIAL 10MG/5ML |
| DOXORUBICIN HYDROCHLORIDE SOLUTION FOR INJECTION VIAL 50MG/25ML |
| EPIRUBICIN HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 100MG/50ML |
| EPIRUBICIN HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 200MG/100ML |
| EPIRUBICIN HYDROCHLORIDE SOLUTION FOR INJECTION VIAL 10MG/5ML |
| EPIRUBICIN HYDROCHLORIDE SOLUTION FOR INJECTION VIAL 50MG/25ML |
| EPIRUBICON HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 200MG/100ML |
| ETOPOSIDE SOLUTION FOR INFUSION VIAL 100MG/5ML |
| ETOPOSIDE SOLUTION FOR INFUSION VIAL 500MG/25ML |
| FLUDARABINE PHOSPHATE SOLUTION FOR INJECTION VIAL 50MG/2ML |
| FLUOROURACIL SOLUTION FOR INFUSION VIAL 1G/20ML (5%) |
| FLUOROURACIL SOLUTION FOR INFUSION VIAL 2.5G/100ML (2.5%) |
| FLUOROURACIL SOLUTION FOR INFUSION VIAL 2.5G/50ML (5%) |
| FLUOROURACIL SOLUTION FOR INFUSION VIAL 500MG/10ML (5%) |
| FLUOROURACIL SOLUTION FOR INFUSION VIAL 500MG/20ML (2.5%) |
| FLUOROURACIL SOLUTION FOR INFUSION VIAL 5G/100ML (5%) |
| GANCICLOVIR POWDER FOR SOLUTION FOR INFUSION VIAL 500MG |
| GEMCITABINE CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 1G/10ML (100MG/ML) |
| GEMCITABINE CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 1G/26.3ML (38MG/ML) |
| GEMCITABINE CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 200MG/2ML (100MG/ML) |
| GEMCITABINE CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 200MG/5.3ML (38MG/ML) |
| GEMCITABINE CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 2G/20ML (100MG/ML) |
| GEMCITABINE CONCENTRATE FOR SOLUTION FOR INFUSION VIAL 2G/52.6ML (38MG/ML) |
| GEMCITABINE POWDER FOR SOLUTION FOR INFUSION VIAL 1G |
| GEMCITABINE POWDER FOR SOLUTION FOR INFUSION VIAL 200MG |
| IDARUBICIN HYDROCHLORIDE SOLUTION FOR INJECTION VIAL 10MG/10ML |
| IDARUBICIN HYDROCHLORIDE SOLUTION FOR INJECTION VIAL 5MG/5ML |
| IRINOTECAN HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 100MG/5ML |
| IRINOTECAN HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 300MG/15ML |
| IRINOTECAN HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 40MG/2ML |
| IRINOTECAN HYDROCHLORIDE SOLUTION FOR INFUSION VIAL 500MG/25ML |
| MELPHALAN POWDER AND SOLVENT FOR SOLUTION FOR INJECTION VIAL 50MG |
| MESNA SOLUTION FOR INJECTION AMPOULE 1G/10ML |
| MESNA SOLUTION FOR INJECTION AMPOULE 400MG/4ML |
| METHOTREXATE SOLUTION FOR INJECTION VIAL 1G/10ML |
| METHOTREXATE SOLUTION FOR INJECTION VIAL 500MG/20ML |
| METHOTREXATE SOLUTION FOR INJECTION VIAL 50MG/2ML (FOR IV, IM AND INTRATHECAL USE) |
| METHOTREXATE SOLUTION FOR INJECTION VIAL 5G/50ML |
| METHOTREXATE SOLUTION FOR INJECTION VIAL 5MG/2ML (FOR IV, IM AND INTRATHECAL USE) |
| MITOMYCIN POWDER FOR SOLUTION FOR INJECTION VIAL 10MG |
| MITOMYCIN POWDER FOR SOLUTION FOR INJECTION VIAL 20MG |
| MITOMYCIN POWDER FOR SOLUTION FOR INJECTION VIAL 40MG |
| MITOXANTRONE SOLUTION FOR INFUSION VIAL 20MG/10ML |
| MITOXANTRONE SOLUTION FOR INFUSION VIAL 25MG/12.5ML |
| OXALIPLATIN SOLUTION FOR INFUSION VIAL 100MG/20ML |
| OXALIPLATIN SOLUTION FOR INFUSION VIAL 200MG/40ML |
| OXALIPLATIN SOLUTION FOR INFUSION VIAL 50MG/10ML |
| PACLITAXEL ALBUMIN POWDER FOR SUSPENSION FOR INFUSION VIAL 100MG |
| PACLITAXEL SOLUTION FOR INFUSION VIAL 100MG/16.7ML |
| PACLITAXEL SOLUTION FOR INFUSION VIAL 150MG/25ML |
| PACLITAXEL SOLUTION FOR INFUSION VIAL 300MG/50ML |
| PACLITAXEL SOLUTION FOR INFUSION VIAL 30MG/5ML |
| PEMETREXED POWDER FOR SOLUTION FOR INFUSION VIAL 100MG |
| PEMETREXED POWDER FOR SOLUTION FOR INFUSION VIAL 500MG |
| PEMETREXED SOLUTION FOR INFUSION VIAL 1000MG/40ML |
| PEMETREXED SOLUTION FOR INFUSION VIAL 100MG/4ML |
| PEMETREXED SOLUTION FOR INFUSION VIAL 500MG/20ML |
| PEMETREXED SOLUTION FOR INFUSION VIAL 850MG/34ML |
| PENTAMIDINE ISETIONATE POWDER FOR SOLUTION FOR INJECTION VIAL 300MG |
| THIOTEPA POWDER FOR SOLUTION FOR INJECTION VIAL 100MG |
| THIOTEPA POWDER FOR SOLUTION FOR INJECTION VIAL 15MG |
| TOPOTECAN SOLUTION FOR INFUSION VIAL 1MG/1ML |
| TOPOTECAN SOLUTION FOR INFUSION VIAL 4MG/4ML |
| VINBLASTINE SULFATE SOLUTION FOR INJECTION VIAL 10MG/10ML |
| VINCRISTINE SULFATE SOLUTION FOR INJECTION VIAL 1MG/1ML |
| VINCRISTINE SULFATE SOLUTION FOR INJECTION VIAL 2MG/2ML |
| VINORELBINE SOLUTION FOR INFUSION VIAL 10MG/1ML |
| VINORELBINE SOLUTION FOR INFUSION VIAL 50MG/5ML |
| ZICONOTIDE SOLUTION FOR INFUSION 100MICROGRAMS/1ML |
| ZICONOTIDE SOLUTION FOR INFUSION 500MICROGRAMS/5ML |
|  |

1. **Phenylephrine, Fludarabine & Zoledronic Acid**

The following products have been included in this procurement:

DBP040 PHENYLEPHRINE SOLUTION FOR INJECTION AMPOULE 10MG/1ML

Offerors should note that DBP002 Phenylephrine Hydrochloride Solution for Injection Amp 10mg/1ml will also be accepted against this description and either product will be awarded in line with the award criteria stated in Document No. 02 Terms of Offer.

DHA377 FLUDARABINE PHOSPHATE SOLUTION FOR INJECTION VIAL 50MG/2ML

Offerors should note that DHA371 FLUDARABINE PHOSPHATE POWDER FOR SOLUTION FOR INJECTION VIAL 50MG will also be accepted against this description and either product will be awarded in line with the award criteria stated in Document No. 02 Terms of Offer.

DFF024 ZOLEDRONIC ACID SOLUTION FOR INFUSION BAG 4MG/100ML

DFF028 ZOLEDRONIC ACID SOLUTION FOR INFUSION BAGS 5MG/100ML

Offerors should note that DFF025 ZOLEDRONIC ACID SOLUTION FOR INJ BOTTLE 4MG/100ML & DFF087 ZOLEDRONIC ACID INFUSION BOTTLE 5MG/100ML will also be accepted against this description and either product will be awarded in line with the award criteria stated in Document No. 02 Terms of Offer.