**Document No. 00 – Read Me First Document**

**Invitation to offer for NHS National Generic Pharmaceuticals - Dasatinib and Paliperidone Injection**

**Offer reference number: CM/PHG/22/5694**

**FIND A TENDER (FTS) - 2023/S 000-001392**

**Period of framework agreement: The total maximum duration of the framework agreement to be no more than 21 months** 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/22/5694/00 - Dasatinib**

**CESW 01/05/2023 – 30/04/2024 – (12 Months)**

**LSNE 01/05/2023 – 30/04/2024 – (12 Months)**

**NWLN 01/05/2023 – 30/04/2024 – (12 Months)**

**CM/PHG/22/5694/01 - Paliperidone Injection:**

**LSNE 01/05/2023 – 31/05/2024 (13 Months)**

**NWLN 01/05/2023 – 31/01/2025 (21 months)**

**THIS DOCUMENT PROVIDES IMPORTANT INFORMATION RELATING TO THE ABOVE TENDER.**

OFFERORS ARE ADVISED THAT THIS DOCUMENT SUPPLEMENTS AND **DOES NOT** REPLACE THE TENDER DOCUMENT SET IN FULL OR IN PART. IT SHOULD NOT, THEREFORE, BE READ IN PLACE OF, OR IN ISOLATION FROM THE COMPLETE TENDER DOCUMENT SET.

**FAILURE TO COMPLY WITH SOME ASPECTS OF THIS INFORMATION MAY INVALIDATE OFFERS.**

1. **PharmaQC completion and Pharmaceutical Quality Assessments (PQA)**

Important information – The PQA process outlined in this tender was newly introduced on a previous tender. The Authority would draw offerors attention to the significantly high failure rates from offerors to comply with the requirements on a previous tender. The Authority advises that it does not intend to apply the permitted clarifications that were undertaken on a previous tender to this tender. As such it stresses the importance of compliance with these requirements and the need to clarify any ambiguities with the Authority through the Atamis system at the earliest opportunity.

Offerors must fully familiarise themselves with the requirements of the Quality Assurance Process as outlined in the Procurement Documents including in Document No. 02 Terms of Offer and Document No.4 Contract Technical Specification for Licensed Medicines. In particular the requirements for offerors to upload the correct specified images and product details by the tender closing date and time. Failure to comply with the full and ongoing Pharmaceutical Quality requirements may invalidate offers.

Each NPCode has been assigned a risk level ‘N – Normal’ or ‘E – Elevated’. The risk level at the commencement of the tender is identified within Document No. 05a(i); 05a(iii); and 05a(v) – Product Listing and Usage. The associated Quality Assessment Process for products based on their risk level is documented within the Procurement Documents including in Document No. 02 Terms of Offer and Document No.4 Contract Technical Specification for Licensed Medicines

1. **PharmaQC registrations**

Offerors MUST register their product on PharmaQC under the NPCode which meets the offered product description in terms of molecule; pack size; strength; volume; form and presentation. This applies even where the offered product is different to the tendered product – the PharmaQC registration MUST reflect the offered product and not the tendered product. Please see also 4 below for information on how an offer should be made in such instances.

1. **How to offer alternatives to the tendered product.**

Offerors are reminded that where they wish, within the limitations of the tender, to offer an alternative pack size, the Selectt offer tool allows this – please put the offered pack size into your offer and not the tendered pack size (the system may ask you to confirm but this is to check you have not made an error). Where offerors wish to offer alternative presentations/strengths/volumes which are not supported by the Selectt offer tool, for example to offer an ampoule presentation against a tendered vial presentation, then this should be clearly noted in the Remarks field of the Selectt offer file and supported by a covering letter submitted as part of the tender. Failure to do so may invalidate your offer as the Authority cannot be held responsible for an incorrect offer.

1. **Additional Requirements – Document No. 04 – Contract Technical Specification Appendix 2**

The NHS has outlined additional specification requirements within an Appendix (Appendix 2) to Document No. 04 – Contract Technical Specification. Failure to comply with the full product specifications may invalidate offers.

1. **Delivery**

All offered prices must be inclusive of delivery. Additional delivery charges will not be accepted. Please refer to the Procurement Documents including Document No. 03.

1. **Continuity of supply and Stock Holding Requirements**

Document No. 02 – Terms of Offer, paragraph 18 – Continuity of Supply post-award of Framework Agreements provides information on: a) termination; b) stock holding; and c) performance levels.

The contractual obligations and consequence of failure are detailed in Document No.03:

* Clause 6 of Schedule 2 – Condition precedent;
* Clause 7 of Schedule 2 – Initial Stock Level and Contract Stock Level;
* Clause 8 of Schedule 2 – Stock Level Failure and reporting;
* Clause 24 of Schedule 2– Service Failures; and
* Schedule 5 Part A – Key Performance Indicators.