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

**Project title: NHS National Pharmaceuticals Generic Products - Hospital Only (Wave 14a) products**

**Offer reference number: CM/PHG/22/5657**

**Period of framework agreement: The total maximum duration of the framework agreement to be no more than 24 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:**

**Hospital Only Products:**

**DLN & DNW 01/02/2023 - 31/01/2025 (24 Months)**

**Housekeeping Products (Hospital Only):**

**CESW 01/02/2023 - 30/09/2023 (8 Months) LSNE 01/02/2023 - 31/05/2024 (16 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. **Procurement for generic drugs**

This procurement is for a variety of drugs, we would like to bring the following information, pertinent to the specific drugs within this procurement to your attention.

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| EVEROLIMUS (AFINITOR OR EQUIVALENT) TABLET 10MG |
| EVEROLIMUS (AFINITOR OR EQUIVALENT) TABLET 2.5MG |
| EVEROLIMUS (AFINITOR OR EQUIVALENT) TABLET 5MG |

For use in all indications as per the reference product, Afinitor®.

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

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. 04a – Quality Assurance Process. In particular the requirements for offerors to upload the correct specified images and product details by the date(s) and time(s) specified. 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); and 05a(iii) – 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. 04a – Quality Assurance Process.

Further clarification will be provided in a Frequently Asked Questions (FAQs) document which will be issued via Atamis as a broadcast message. Please read carefully. If, after reading this document, offerors are unclear about the requirement please submit a question through the Atamis Portal so that a full response can be provided and shared with all offerors.

1. **Estimated annual volumes**

Within Tender Documents No. 05a(i); and 05a(iii) The Authority has provided estimated annual volumes. However, the Authority does remind offerors that any estimated annual volumes are provided by the Authority as outlined in Document No. 02 – Terms of Offer, Paragraph 2.3. However, if the estimated annual volumes for a product which you wish to offer against appear inaccurate please submit a question through the Atamis Portal so that they can be reviewed accordingly.

1. **Additional Requirements – Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements**

The NHS has outlined additional specification requirements within an Appendix (Appendix A) to Document No. 04b. 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. 3.

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. 3:

* Clause 6 of Schedule 2 – Condition(s) precedent;
* Clause 7 of Schedule 2 – Initial Stock Level and Contract Stock Level;
* Clause 8 of Schedule 2 – Stock Level Failure and reporting;
* Clause 23 of Schedule 2– Service Failures; and
* Schedule 5 Part A – Key Performance Indicators.