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

**Project title: NHS National Pharmaceuticals Generic Products – 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)

**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 Graphic Design for Safety Assessments (GDA)**

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, Document No. 04a – Quality Assurance Process and Document No. 07b – Quality Assurance Policy. 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.

This procurement includes a new edition of Document No. 07b – Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines. Offers are advised to familiarise themselves with this document including Appendix 1 – Fixed Gateway Criteria.

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 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 this document 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); 05a(iii) and 05a(v), 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 Document No. 04b. Failure to comply with the full product specifications may invalidate offers.

Offerors are advised to familiarise themselves with the contents Document No. 04b as there have been some additions to this document relating to this procurement.

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 14 of Schedule 1 – Condition(s) Precedent
* Clause 15 and 16 of Schedule 1 – Initial Stock Level and Framework Stock Level
* Clause 19 of Schedule 1 – Stock Level Failure and Reporting;
* Clause 19 of Schedule 2 – Service Failures; and
* the Key Performance Indicators set out at Schedule 5 Part A of the Framework Agreement.

1. **UK-wide licensing for human medicines**

Offerors are advised to be aware of the following guidance regarding the changes to the licensing of medicines for human use in the UK following the agreement of the Windsor Framework which will be implemented from 1st January 2025. Link provided below:

[UK-wide licensing for human medicines - GOV.UK (www.gov.uk)](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fuk-wide-licensing-for-human-medicines%2Fuk-wide-licensing-for-human-medicines&data=05%7C02%7Crachel.williams11%40nhs.net%7C3db34b33332248f8141a08dc978a80d3%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638551868312635281%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=T1%2FhanKiQ%2Bdewacm04agIJUhS3H6iwXSxNbml2Iw6zs%3D&reserved=0)