**Document No. 02**

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

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

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:**

**Hospital Only Products: DLN: 01/02/2023 to 31/01/2025 (24 months)**

 **DNW: 01/02/2023 to 31/01/2025 (24 months)**

**Hospital Only Products (housekeeping): CESW: 01/02/2023 to 30/09/2023 (8 months)**

 **LSNE: 01/02/2023 to 31/05/2024 (16 months)**

**Terms of offer**

1. **The Commercial Medicines Unit**

1.1 NHS England, (‘Authority’) is conducting this procurement exercise as a central purchasing body to establish a framework agreement (the ‘Framework Agreement’) for and on behalf of the Participating Authorities with whom the suppliers appointed to the Framework Agreement (‘Successful Offerors’) will ultimately enter into contracts under the Framework Agreement for the supply of the goods and/or services. The Participating Authorities are the organisations specified in Schedule 8 (*Participating Authorities*) of Document No. 03 Framework Agreement and Terms and Conditions.

1.2 The Authority will not be a party to any such subsequent contracts under the Framework Agreement. In accordance with Regulation 37 of the Public Contracts Regulations 2015, each Participating Authority is and shall remain responsible for the conduct of its award of contracts under the framework agreement, including (but not limited to) fulfilling the requirements imposed by Regulation 33 of the Public Contracts Regulations 2015 when conducting an award of contract(s) under the framework agreement.

1.3 The Authority is not responsible or accountable for and shall have no liability whatsoever in relation to:

 1.3.1 The conduct of Participating Authorities in relation to the framework agreement;

1.3.2 the acts or omissions of a Participating Authority in connection with a contract between the successful Offeror and the Participating Authority entered into pursuant to the framework agreement; or

1.3.3 The performance or non-performance of a contract between the successful Offeror and the Participating Authority entered into pursuant to the framework agreement.

1.4 Offerors taking part in this competition consent to the terms set out in this Invitation to Offer as part of the competition process.

**2. The framework agreement**

2.1 This procurement exercise concerns the establishment of a Framework Agreement under which one or more successful Offerors will be appointed to supply goods and/or services on the terms agreed to such of the Participating Authorities as may place orders for such goods and/or services from time to time.

2.2 The Authority cannot mandate any Participating Authority to place any orders or any particular level of orders, nor can it require them to place orders with particular successful Offerors. It follows that the Authority can give no warranty that any successful Offeror will receive any business or any particular level of business under the framework agreement.

2.3 Any volume estimates provided to Offerors by Authority are statements of opinion, provided in good faith and based on past experience and market knowledge, but they should not be relied upon by Offerors in formulating their offers.

2.4 By submitting an Offer, an Offeror is deemed to acknowledge and agree that:

2.4.1 the supply of goods and/or services under any framework agreement resulting from this procurement exercise is not an exclusive arrangement; and

2.4.2 notwithstanding the establishment of any framework agreement pursuant to this procurement exercise, the Authority and/or any of the Participating Authorities may at any time purchase goods and/or services from (and/or enter into other contracts and framework agreements with) any third party that are the same as, or similar to, the goods and/or services described in the Document No. 05a(ii) and Document No. 05a(iv) of the tender pack.

**3. Information and confidentiality**

3.1 Information that is supplied to Offerors as part of the procurement exercise is supplied in good faith. However, Offerors must satisfy themselves as to the accuracy of such information and no responsibility is accepted for any loss or damage of whatever kind or howsoever caused arising from the use by the Offerors of such information (including but not limited to any claim in tort (including negligence), contract or quasi-contract, restitution or other equitable claim, breach of statutory duty, misrepresentation, judicial review or other public law remedy, or any other type of claim whatsoever) unless such information has been supplied fraudulently by the Authority.

3.2 All information supplied to Offerors by the Authority in connection with this procurement exercise shall be regarded as confidential. By receiving information in any manner whatsoever in relation to this procurement exercise, Offerors agree to be bound by the obligation to preserve the confidentiality of all such information.

* 1. All Central Government Departments and their Executive Agencies and Non Departmental Public Bodies are subject to control and reporting within Government. In particular, they report to the Cabinet Office and HM Treasury for all expenditure. Further, the Cabinet Office has a cross-Government role delivering overall Government policy on public procurement - including ensuring value for money and related aspects of good procurement practice.
	2. For these purposes, the Authority may disclose within Government any of the Offerors documentation or information (including any that the Offeror considers to be confidential and/or commercially sensitive such as specific bid information) submitted by the Offeror to the Authority during this Procurement. The information will not be disclosed outside Government (other than as required by the Freedom of Information Act 2000 or other legal obligation).

3.5 This invitation and its accompanying documents shall remain the property of the Authority and shall be returned to the Authority on demand.

**4. Freedom of Information Act 2000**

4.1 The Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations 2004 (refer to as ‘FOIA) applies to the Authority.

## 4.2 Offerors should be aware of the Authority’s obligations and responsibilities under the FOIA to disclose, on request, recorded information held by the Authority. Information provided by Offerors in connection with this procurement exercise, or in connection with any Framework Agreement that may be concluded as a result of this exercise, may therefore have to be disclosed by the Authority in response to such a request, unless the Authority decides that one of the statutory exemptions under the FOIA applies. The Authority may also include certain information in the NHS England freedom of information publication scheme. Further information can be found at <https://www.england.nhs.uk/contract-us/pub-scheme>

4.3 In certain circumstances, and in accordance with the Code of Practice issued under section 45 of the FOIA and/or the Environmental Information Regulations 2004, the Authority may consider it appropriate to ask Offerors for their views as to the release of any information before a decision on how to respond to a request is made. In dealing with requests for information under the FOIA, the Authority must comply with a strict timetable and the Authority would, therefore, expect a timely response to any such consultation within five working days (a working day being any day of the week from Monday to Friday excluding Bank holidays in England).

4.4 If Offerors provide any information to the Authority in connection with this procurement exercise, or with any framework agreement that may be concluded as a result of this exercise, which is confidential in nature and which an Offeror wishes to be held in confidence, then Offerors must clearly identify in their offer documentation the information to which Offerors consider a duty of confidentiality applies. Offerors must give a clear indication which material is to be considered confidential and why it is considered to be so, along with the time period for which it is requested to remain confidential in nature. Such indications by Offerors shall also include the section number in FOIA for the applicable exemption and where the proposed exemption is classified as a qualified exemption under FOIA, Offerors must indicate clearly why they think that the result of the public interest test applicable under FOIA should be that the information is exempt. This information should be listed in Document No.8 (Confidential Information Schedule). The use of blanket protective markings such as “commercial in confidence” will no longer be appropriate. In addition, marking any material as “confidential” or equivalent should not be taken to mean that the Authority accepts any duty of confidentiality by virtue of such marking. Please note that even where an Offeror has indicated that information is confidential, the Authority may be required to disclose it under the FOIA if a request is received.

4.5 The Authority cannot accept that trivial information or information which by its very nature cannot be regarded as confidential should be subject to any obligation of confidence.

4.6 In certain circumstances where information has not been provided in confidence, the Authority may still wish to consult with Offerors about the application of any other exemption such as that relating to disclosure that will prejudice the commercial interests of any party.

4.7 The decision as to which information will be disclosed is reserved to the Authority, notwithstanding any consultation with Offerors.

**5. Right to publish – Transparency agenda**

5.1 By submitting an Offer, an Offeror is deemed to acknowledge and agree that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, this Invitation to Offer and the content of any framework agreement resulting from this procurement exercise will be published in accordance with the Government's policies on transparency as expounded in the Guidance published by the Cabinet Office. Further information on transparency can be found at:

<https://www.gov.uk/government/policies/buying-and-managing-government-goods-and-services-more-efficiently-and-effectively>

5.2 The Authority shall be ultimately and solely responsible for determining whether any of the content of this Invitation to Offer and any Framework Agreement that is concluded as a result of this procurement exercise is exempt from disclosure in accordance with the provisions of the FOIA.

**6. Samples**

6.1 Offerors will not be required to submit physical samples of each item offered against this tender at this time, however the Authority retains the right to request samples should the Authority decide they will be required. Any such samples shall be provided free of charge.

6.2 Pharmaceutical Quality Assessments, where required, will be made against the most current uploaded files on PharmaQC.

* 1. Offerors **must** fully register any offered item on PharmaQC (the Authority’s electronic application for gathering product details and organising QA assessments). All required information/images for Part A MUST be uploaded to PharmaQC by tender close otherwise it will invalidate your offer.

6.4 Please refer to Document No. 04a Quality Assurance Process which details all requirements for Pharma QC registration, approved artwork and photographs.

6.5 It is the full responsibility of Offerors to make sure that the images uploaded to PharmaQC represent the offered item(s) and are registered against the offered NPCode.

**7. Prices**

7.1 Prices must be stated in the offer schedules and must remain open for acceptance until **90** days from the closing date for the receipt of offers.

7.2 Prices must be firm (i.e. not subject to variation) for the duration of any framework agreement that may result from this procurement exercise subject only to any variation provisions contained in the framework agreement and documents incorporated within it.

7.3 Prices must be quoted in sterling (GBP) and exclusive of Value Added Tax.

7.4 Prices for offered products must be inclusive of delivery to the trust as required in Document No. 03, Schedule 2 of the “Call-Off Terms and Conditions”.

8 **Requirement and Lot Structure**

8.1 This procurement concerns the procurement of “Hospital Only” products; and “Hospital Only - Housekeeping” products. The procurement is sub-divided into lots.

8.2 For the Hospital Only products (CM/PHG/22/5657/02) two Regions are being tendered (see Table 1 below). As stated in 8.3 there is no Oral products (CM/PHG/22/5657/01) tender within this Procurement. For Hospital Only housekeeping products (CM/PHG/22/5657/03) up to two Regions are being tendered with CESW representing one individual region and LSNE representing one individual region. Each Lot is deemed to be a separate entity. An Offeror may be awarded one or more Lots (refer to Clause 8.9 for further explanation):

 **Table 1**

| **LOT** | **REGION** |
| --- | --- |
| **LOT 1** |
| Hospital Only Products – (CM/PHG/22/5657/02) | DLN |
| Hospital Only Housekeeping Products – (CM/PHG/22/5657/03) | CESW |
| **LOT 2** |
| Hospital Only Products – (CM/PHG/22/5657/02) | DNW |
| Hospital Only Housekeeping Products – (CM/PHG/22/5657/03) | LSNE |

* 1. There is no Oral (plus non-parenteral) products tender within this Procurement.
	2. The composition of each Region (and therefore the potential range of Participating Authorities in each Lot) is described in more detail in Schedule 8 (Participating Authorities)) of Document No. 03 (Framework Agreement and Terms and Conditions).
	3. A detailed description of the goods and/or services that an Offeror will be required to supply for a Lot in which it has been successful is set out in the offer schedules and Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements.

8.6 Each National Product Code product description listed in the offer schedules, shall be a **Product** for the purposes of this Invitation to Offer.

8.7 The tender comprises the following offer schedules:

8.7.1 **CM/PHG/22/5657/02 (Document No. 05a(ii)) – NHS National Pharmaceuticals – Hospital Only Products:**

For each Product comprised in this offer schedule, Document No. 05a(i) specifies the Lot(s) being tendered in this competition.

**Please note that this reference to ‘Lot’ in the SELECTT tender tool does equate to a Lot as defined in Table 1 above.**



**In this example each Lot relates to the specific regional buying groups as defined in Table 1 above. Where offerors are offering for all tendered Lots they should insert the price in each of the Lots above. Should a supplier not wish to offer for all tendered Lots but to restrict their offer to a specific Lot(s) then they should insert the price against the specific Lot(s) only. Where a supplier wishes to offer for less than the total number of Lots available but does not wish to be specific about which Lots it wishes to offer for then the supplier should offer the price against all of the Lots on the Selectt offer schedule and insert the comment “Not Lot specific” in the remarks field, such offers should additionally be supported by including an explanatory note when the supplier uploads their offer(s). For the avoidance of doubt any such offers will be dealt with as per the Award Criteria and awarded on the basis of MEAT, where applicable. Please refer to Paragraph 8.8 regarding offer prices.**

8.7.2 **CM/PHG/22/5657/03 (Document No. 05a(iv)) – NHS National Pharmaceuticals – Hospital Only (housekeeping) Products:**

For each Product comprised in this Offer Schedule, Document No. 05a(iii) specifies the Lot(s) being tendered in this competition.

**Please note that this reference to "Lot" in the SELECTT tender tool DOES equate to a Lot, as identified in Table 1 above.**



 **In this example each Lot relates to the specific regional buying groups as defined in Table 1 above. Where offerors are offering for all tendered Lots they should insert the price in each of the Lots above. Should a supplier not wish to offer for all tendered Lots but to restrict their offer to a specific Lot(s) then they should insert the price against the specific Lot(s) only. Where a supplier wishes to offer for less than the total number of Lots available but does not wish to be specific about which Lots it wishes to offer for then the supplier should offer the price against all of the Lots on the Selectt offer schedule and insert the comment “Not Lot specific” in the remarks field, such offers should additionally be supported by including an explanatory note when the supplier uploads their offer(s). For the avoidance of doubt any such offers will be dealt with as per the Award Criteria and awarded on the basis of MEAT, where applicable. Please refer to Paragraph 8.8 regarding offer prices.**

8.8 Offerors have the opportunity to bid for all (or any) of the Lots specified in the offer schedules. **Offerors shall only submit one offer price per Product, irrespective of the number of Lots specified in the offer schedule.**

8.9 To ensure a diverse range of suppliers, the Authority may limit the number of Lots that may be awarded to one supplier as follows:

8.9.1 In respect of each Product listed in the “Hospital Only” Products tender (CM/PHG/22/5657/02) and “ Hospital Only (Housekeeping)” Products tender (CM/PHG/22/5657/03) where Document No. 05a(i) or 05a(iii) specifies that both Lots are being tendered, the following restrictions shall apply, subject to paragraph 12.2.3:

1. where two or more compliant offers that meet the qualitative criteria (and, as more particularly described in paragraph 12.2.3, the second ranked offer does not exceed 125% of the median of compliant offered prices) are received, a maximum of one Lot may be awarded to one supplier;
2. where only one compliant offer that meets the qualitative criteria is received, both Lots may be awarded to one supplier.

8.10 In respect of each Product in each Lot or Region, unless otherwise notified, this procurement will establish a single supplier framework agreement.

**9. Offer documentation and submission**

9.1 Offers may be submitted for all goods and/or services or for selected items.

9.2 The goods and/or services offered by Offerors must be strictly in accordance Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements. Goods and/or services of essential similarity may be offered but all differences between such items and the Specification must be indicated in detail in the Offer schedule.

* 1. CMU’s Selectt programme shall be used by Offerors to create the offer documents for this procurement exercise. Instructions on accessing and using this system can be found at the following web link:

<https://www.gov.uk/government/publications/drugs-and-pharmaceutical-supplier-tender-submission>

* 1. Offers must comprise:
		1. the completed Response form on the Atamis website – found under “My Proposals and Quotes”

9.4.2 The offer schedule in .cmu format – Document No. 05a(ii) and Document No. 05a(iv) of the tender pack, Selectt bid file(s), with the titles respectively:

CM\_PHG\_22\_5657\_02\_xxx.cmu

CM\_PHG\_22\_5657\_03\_xxx.cmu

Where xxx represents your organisations’ tendering supplier code:

* + 1. the Form of Offer (Document No. 06 to be completed on the Atamis website)
		2. the uploading of the relevant documentation and information to PharmaQC as required by section 6 of this Document No.02 and Document No.4a Quality Assurance Process
		3. the Quality control technical sheet (Document No. 07a to be completed on the Atamis website)
		4. the Confidential Information Schedule (Document No. 08), if any types of information are considered to be confidential by the Offeror;
		5. a statement of prompt settlement discounts, if available;
		6. details of the Offeror’s ability, if any, to trade electronically;
		7. Confirmation that any information previously supplied to the Authority in connection with the offer is still accurate and is incorporated by reference into the offer.
		8. The Required Stability Information (Document No. 09 - Stability Data Requirements) and appropriate supporting documentation where applicable. Supporting evidence must be provided for extended shelf life if not already within the SmPC, in the form of either:
1. A statement from the Marketing Authorisation Holder’s QP; or
2. A study that is in compliance with the principles of Standard Protocol for Deriving and Assessment of Stability – Part 1 Aseptic Preparation (Small Molecules) (Ed. 5 Sept 2019).
3. Other, where (i) and/or (ii) above are not available and offerors are submitting a proposed alternative please complete the document accordingly.
	1. The Form of offer must be approved via the Authority’s electronic tendering system by an officer duly authorised by the Offeror.
	2. The Form of Offer and other documents referred to in paragraph 9.4 above must be completed in full. Any offer may be rejected which -

9.6.1 contains gaps, omissions or obvious errors; or

9.6.2 is received after the closing time and date for the receipt of offers.

* 1. For clarification in completing the offer documentation, or commercial and/or technical queries please send a message via the Atamis messaging portal: health.atamis.co.uk

Please note that any queries raised by Offerors and the responses to those queries by the Authority may be published anonymously to all Offerors in order to ensure transparency, fairness and equal treatment of Offerors throughout the procurement exercise. If you are concerned that your query and/or the response to it may disclose confidential information or information which is commercially damaging to you, then you may submit the query marked "Confidential" and setting out clearly the reasons why you believe that the query and/or the response are or will be confidential or commercially damaging. The Authority will consider your request and make its decision at its sole discretion. If the Authority determines that the query or response should not be disclosed to other Offerors, it will answer your query and not disclose it or the response (as appropriate) to the other Offerors. If the Authority determines that the query and/or the response should be disclosed to other Offerors, it will give you the chance either to withdraw your query or have it answered. If the latter, then the Authority will disclose the query and the response to all other Offerors.

* 1. Offers and all documents relating to the offers must be written in English and submitted to the Authority via the Authority’s electronic tendering system by **13:00 hours on Tuesday 18th October 2022.**

# **10.** **The Authority’s Rights**

10.1 The Authority reserves the right to:

10.1.1 waive or change the requirements of this Invitation to Offer from time to time without prior (or any) notice being given by the Authority;

10.1.2 seek clarification or documents in respect of an Offeror's submission;

10.1.3 disqualify any Offeror that does not submit a compliant Offer in accordance with the instructions in this Invitation to Offer;

10.1.4 disqualify any Offeror that is guilty of serious misrepresentation in relation to its Offer or the procurement process;

* + 1. withdraw this Invitation to Offer at any time, or re-invite Offers on the same or any alternative basis;
		2. accept an Offer either in whole or in part, each item being for this purpose treated as offered separately;
		3. choose not to award any framework agreement as a result of the procurement process for any reason;
		4. make whatever changes it sees fit to the timetable, structure or content of the procurement process, depending on approvals processes or for any other reason; and/or
		5. at any time terminate the procurement process for any reason.

**11. Warnings and disclaimers**

11.1 While the information contained in this Invitation to Offer is believed to be correct at the time of issue, neither the Authority, its employees or advisors, nor any participating authority accept any liability for its accuracy, adequacy or completeness, nor will any express or implied warranty be given. This exclusion extends to liability in relation to any statement, opinion or conclusion contained in or any omission from this Invitation to Offer and in respect of any other written or oral communication transmitted (or otherwise made available) to any Offeror. This exclusion does not extend to any fraudulent misrepresentation made by or on behalf of the Authority.

11.2 If an Offeror proposes to enter into a framework agreement with the Authority, it must rely on its own enquiries and on the terms and conditions set out in the Framework Agreement(s) (as and when finally executed), subject to the limitations and restrictions specified in it.

11.3 Neither the issue of this Invitation to Offer, nor any of the information presented in it, should be regarded as an offer, commitment or representation on the part of the Authority (or any other person) to enter into a contractual arrangement.

**12.** **Contract award criteria and award methodology**

12.1**Award Criteria**

12.1.1 Any framework agreement(s) awarded as a result of this procurement shall be awarded on the basis of the offer that is most economically advantageous to the Authority (MEAT) and which satisfies the Quality Criteria, each as set out in paragraph 12.1.5 and Table 1 below, in accordance with this Invitation to Offer. Where a framework agreement award is made, each Product within the Lot shall be awarded separately; i.e. each Product within the Lot will form a separate single supplier framework arrangement.

12.1.2 With the exception of those Products listed at Paragraph 12.1.4 below, the Award Criteria (as described in paragraph 12.1.5 and Table 1 below) will be applied separately in relation to each of the Lots for the Hospital Only and Hospital Only Housekeeping products.

12.1.3 Any award(s) shall be made in accordance with:

1. the award criteria described at paragraph 12.1.5 below;
2. the award methodology described at paragraph 12.2 below; and
3. the lotting strategy described at paragraph 8.9 above.

on the basis of the lowest cost solution for the Authority for all of the Lots being tendered (for the Product), where cost is calculated by multiplying the offer price tendered by the Offeror (for the Product) by the estimated volumes for the Lot(s) being tendered for the Product (anticipated for the duration of the agreement excluding any extension period) for the Product.

12.1.4 For the following Products, where the NHS requires different strengths to be mixed (and product liability issues would be complicated by awards to differing Offerors), the Product descriptions shall be combined:

|  |
| --- |
| **Bendamustine Hydrochloride Powder For Solution for Infusion** |
| Bendamustine Hydrochloride Powder For Solution For Infusion Vial 100mg |
| Bendamustine Hydrochloride Powder For Solution For Infusion Vial 25mg |
| **Carboplatin Solution For Infusion** |
| 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 |
| **Cisplatin Solution For Infusion** |
| Cisplatin Solution For Infusion Vial 100mg/100ml |
| Cisplatin Solution For Infusion Vial 50mg/50ml |
| **Cyclophosphamide Powder For Solution For Infusion** |
| Cyclophosphamide Powder For Solution For Injection Vial 1g |
| Cyclophosphamide Powder For Solution For Injection Vial 500mg |
| **Cytarabine Solution For Injection (100mg/ml)** |
| Cytarabine Solution For Injection Vial 1g/10ml |
| Cytarabine Solution For Injection Vial 2g/20ml |
| **Dacarbazine Powder For Solution For Infusion** |
| Dacarbazine Powder For Solution For Infusion Vial 1000mg |
| Dacarbazine Powder For Solution For Infusion Vial100mg |
| Dacarbazine Powder For Solution For Infusion Vial 200mg |
| Dacarbazine Powder For Solution For Infusion Vial 500mg |
| **Docetaxel Solution For Infusion (20mg/ml)** |
| Docetaxel Solution For Infusion Vial 140mg/7ml (20mg/ml) Or 160mg/8ml |
| 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** |
| Doxorubicin Hydrochloride Pegylated Liposomal Solution for Infusion Vial 20MG/10ML |
| Doxorubicin Hydrochloride Pegylated Liposomal Solution for Infusion Vial 50MG/25ML |
| **Doxorubicin Hydrochloride Solution For Injection** |
| Doxorubicin Hydrochloride Solution For Injection Vial 10mg/5ml |
| Doxorubicin Hydrochloride Solution For Injection Vial 50mg/25ml |
| **Epirubicin Hydrochloride Solution For Injection** |
| Epirubicin Hydrochloride Solution For Injection Vial 10mg/5ml |
| Epirubicin Hydrochloride Solution For Injection Vial 50mg/25ml |
| **Etoposide Solution For Infusion** |
| Etoposide Solution For Infusion Vial 20mg/ml 5ml |
| Etoposide Solution For Infusion Vial 500mg/25ml |
| **Fluorouracil Solution For Infusion (50mg/ml 5%)** |
| Fluorouracil Solution For Infusion Vial 2.5g/50ml (5%) |
| Fluorouracil Solution For Infusion Vial 500mg/10ml (5%) |
| Fluorouracil Solution For Infusion Vial 5G/100ml (5%) |
| **Gemcitabine Concentrate For Solution For Infusion (100mg/ml)** |
| Gemcitabine Concentrate For Solution For Infusion Vial 1g/10ml |
| Gemcitabine Concentrate For Solution For Infusion Vial 200mg/2ml |
| Gemcitabine Concentrate For Solution For Infusion Vial 2g/20ml |
| **Gemcitabine Concentrate For Solution For Infusion (38mg/ml)** |
| Gemcitabine Concentrate For Solution For Infusion Vial 1g/26.3ml |
| Gemcitabine Concentrate For Solution For Infusion Vial 200mg/5.3ml |
| Gemcitabine Concentrate For Solution For Infusion Vial 2g/52.6ml |
| **Gemcitabine Powder For Solution For Infusion** |
| Gemcitabine Powder For Solution For Infusion Vial 1g |
| Gemcitabine Powder For Solution For Infusion Vial 200mg |
| **Idarubicin Hydrochloride Injection** |
| Idarubicin Hydrochloride Solution For Injection Vial 10mg/10ml |
| Idarubicin Hydrochloride Solution For Injection Vial 5mg/5ml |
| **Irinotecan Hydrochloride Solution For Infusion** |
| Irinotecan Hydrochloride Solution For Infusion Vial 100mg/5ml |
| Irinotecan Hydrochloride Solution For Infusion Vial 300mg/15ml |
| Irinotecan Hydrochloride Solution For Infusion Vial 40mg/2ml |
| **Methotrexate Solution For Injection (100mg/ml)** |
| Methotrexate Solution For Injection Vial 5mg/50ml |
| Methotrexate Solution For Injection Vial 1g/10ml |
| **Methotrexate Solution For Injection (25mg/ml**) |
| Methotrexate Solution For Injection Vial 500mg/20ml |
| Methotrexate Solution For Injection Vial 50mg/2ml (For IV, IM and Intrathecal Use) |
| **Oxaliplatin Solution For Infusion** |
| Oxaliplatin Solution For Infusion Vial 100mg/20ml |
| Oxaliplatin Solution For Infusion Vial 50mg/10ml |
| **Paclitaxel Solution For Infusion** |
| Paclitaxel Solution For Infusion Vial 100mg/16.7ml |
| Paclitaxel Solution For Infusion Vial 300mg/50ml |
| Paclitaxel Solution For Infusion Vial 30mg/5ml |
| **Pemetrexed Powder For Solution For Infusion** |
| Pemetrexed Powder For Solution For Infusion Vial 100mg |
| Pemetrexed Powder For Solution For Infusion Vial 500mg |
| **Pemetrexed Solution for Infusion** |
| Pemetrexed Solution for Infusion 100mg/4ml |
| Pemetrexed Solution for Infusion 500mg/20ml |
| **Teicoplanin Powder and Solvent For Solution For Injection** |
| Teicoplanin Powder and Solvent For Solution For Injection Vial 200mg |
| Teicoplanin Powder and Solvent For Solution For Injection Vial 400mg |
| **Thiotepa Powder for Solution for Injection** |
| Thiotepa Powder for Solution for Injection Vial 100mg |
| Thiotepa Powder for Solution for Injection Vial 15mg |
| **Vincristine Sulfate Solution For Injection** |
| Vincristine Sulfate Solution For Injection Vial 1mg/1ml |
| Vincristine Sulfate Solution For Injection Vial 2mg/2ml |
| **Vinorelbine Solution For Infusion** |
| Vinorelbine Solution For Infusion Vial 10mg/1ml |
| Vinorelbine Solution For Infusion Vial 50mg/5ml |
| **Ziconotide Solution for Injection** |
| Ziconotide Solution for Infusion 100micrograms/1ml |
| Ziconotide Solution for Infusion 500micrograms/5ml |

 12.1.4.1 The NHS has a requirement for a number of tendered products to have a minimum extended stability for the medicine prepared for administration according to the directions in its SmPC, where available. Some of the products listed at 12.1.4 above are listed within Document No. 09 – Stability data requirements. Any Offeror submitting an Offer for any Product listed in Document No. 09 MUST fully complete the requirement information requested and return the completed Document No. 09 as part of their Offer. Failure to fully provide this information may invalidate Offeror’s submissions for these products.

 12.1.4.2 In respect of the Products referred to in section 12.1.4.1 above, where 1 or more offers are received which meet, as a minimum, the extended stability requirements shown in Document No. 09 – Stability data requirements, the award criteria shall be applied in relation to the molecule/form and awards shall be made in accordance with:

1. the award criteria described at paragraph 12.1.5 below;
2. the award methodology described at paragraph 12.2 below; and
3. the lotting strategy described at paragraph 8.9 above,

on the basis of the lowest cost combination of awards to the Authority (where total cost is calculated by calculating the sum of the costs of the respective Products by multiplying the offer prices tendered by the Offeror for each Product by the estimated volumes for the Lot (anticipated for the duration of the agreement excluding any extension period) for the respective Products.

* + - 1. In respect of the Products referred to in section 12.1.4.1 above, where no compliant offers are received which meet, as a minimum, the extended stability requirements shown in Document No. 09 – Stability data requirements, the Lot will be awarded to the offeror who has the longest evidenced stability for their respective product. Where the same longest evidenced stability for their respective product is offered by more than one offeror the award criteria (described at paragraph 12.1.5 below) shall be applied in relation to the molecule/form and awards shall be made in accordance with:
1. the award criteria described at paragraph 12.1.5 below;
2. the award methodology described at paragraph 12.2 below; and
3. the lotting strategy described at paragraph 8.9 above

on the basis of the lowest cost combination of awards to the Authority (where total cost is calculated by calculating the sum of the costs of the respective Products by multiplying the offer prices tendered by the Offeror for each Product by the estimated volumes for the Lot (anticipated for the duration of the agreement excluding any extension period) for the respective Products).

12.1.4.4 In respect of those products **NOT** shown in section 12.1.4 above but listed in Document No. 09 – Stability data requirements as requiring extended stability, where one or more offers are received which meet, as a minimum, the extended stability requirements shown in Document No. 09 – Stability data requirements, awards shall be made in accordance with:

* + - * 1. the award criteria described at paragraph 12.1.5 below;

(b) the award methodology described at paragraph 12.2 below; and

(c) the lotting strategy described at paragraph 8.9 above,

12.1.4.5 In respect of those products **NOT** shown in section 12.1.4 above but listed in Document No. 09 – Stability data requirements as requiring extended stability, where no compliant offers are received which meet, as a minimum, the extended stability requirements shown in Document No. 09 – Stability data requirements, the Lot will be awarded to the offeror who has the longest evidenced stability available. Where the same longest evidenced stability period is offered by more than one Offeror the awards shall be made, for those in accordance with:

* + - * 1. the award criteria described at paragraph 12.1.5 below;

(b) the award methodology described at paragraph 12.2 below; and

(c) the lotting strategy described at paragraph 8.9 above.

12.1.5 For each Product, the award criteria are as follows:

 (a) **Price criteria of:**

1. sub-criterion (1) - Cost of product;
2. sub-criterion (2) – Cost of product across range **– only to be used in respect of those Products listed at Paragraph 12.1.4;** and

(iii) sub-criterion (3) - Cost of change – **only to be used in the circumstances described in paragraphs 12.2.1 (d)(i) and 12.2.4**

(b) **Qualitative criteria of:**

1. sub-criterion (1) – QA assessment of risk to patient; and
2. sub-criterion (2) – QA assessment of risk to a patient across a range of products; and
3. sub-criterion (3) – Supply route and associated cost – **only to be used in the circumstances described in paragraphs 12.2.1 (d)(ii) and 12.2.5;** and
4. sub-criterion (4) – Extended Stability Data – **only to be used in the circumstance described in Document No. 07b and for the products indicated in Document No. 09**; and
5. sub-criterion (5) – Additional Specification Requirements - **as required in Appendix A of Document No. 04b**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Sub-Criteria** | **Debrief Explanation** |
| **Price** | **Sub-criterion (1)**Cost of product | The successful supplier’s offer was the lowest-priced compliant offer received. |
| **Sub-criterion (2)****This sub-criterion (2) is only applicable in respect of those Products listed at paragraph 12.1.4**Cost of product across range | The successful Offeror’s offer across the identified range of products was the lowest-priced compliant offer received. |
| **Sub-criterion (3)** Cost of change**Only to be used in the circumstances described in paragraphs 12.2.1 (d)(i) and12.2.4** | The successful supplier’s product provides the most economically advantageous offer when the costs associated with change are taken into consideration. Examples of indicators of costs of change may include (but shall not be limited to) the following: * The costs associated with updating pharmacy ordering and stock-holding systems.
* The costs associated with segregating products stocked to avoid co-dispensing where this might be problematic, e.g. two products to one patient.
* The costs associated with changing any ancillary documentation that might be associated with a particular product, e.g. patient information cards, work cards etc.
* The costs associated with assessing and promulgating information pertaining to any specific changes associated with a given product, e.g. storage, handling, differences in excipients or salts or differences in preparation or use of the product.
* The costs associated with explaining any differences between products to the patient, e.g. changes in pack presentation, excipients etc.
 |
| **Quality** | **Sub-criterion (1)****Assessed according to the requirements disclosed in:*** **Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements and Document No. 07b - Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines**
* **where either the Product is:**
	+ **designated as "Elevated" (see Document No.4a Quality Assurance Process); or**
	+ **is designated as "Normal" but is subject to the "Elevated" procedure in accordance with the approach documented in Document No. 4a - Quality Assurance Process,**

**QA assessments that are confirmed by the evaluation panel as “Low Risk” or “Medium Risk” will be deemed to be acceptable for award to the framework agreement (subject to satisfying all other award criteria). Any Product QC assessments that are confirmed by the evaluation panel as “High Risk” or "No Score" will not be deemed acceptable for award to the framework unless there are no other qualifying offers where such Product will only be awarded to the framework in the absence of any other qualifying offers (and subject to satisfying all other award criteria).** | The successful supplier’s product and packaging are in accordance with the criteria detailed in Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements, Document No. 04a - Quality Assurance Process and, where applicable, the Document No. 07b - Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines and therefore less likely to give rise to an increased risk of a medication error and the QA assessment for their product reflects this. |
|  | **Sub-criterion (2)** **Assessed according to the requirements disclosed in:*** **Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements and Document No. 07b - Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines**
* **where either the Product is:**
	+ **designated as "Elevated" (see Document No.4a Quality Assurance Process); or**
	+ **is designated as "Normal" but is subject to the "Elevated" procedure in accordance with the approach documented in Document No.4a Quality Assurance Process,**

**QA assessments that are confirmed by the evaluation panel as “Low Risk” or “Medium Risk” will be deemed to be acceptable for award to the framework agreement (subject to satisfying all other award criteria). Any Product QC assessments that are confirmed by the evaluation panel as “High Risk” only in circumstances where awarded with another strength in the product range (due to a lack of differentiation between the packaging), where the evaluation panel has split the product range will not be deemed acceptable for award to the framework unless there are no other qualifying offers where such Product will only be awarded to the framework in the absence of any other qualifying offers (and subject to satisfying all other award criteria).**  | The successful Offeror's packaging for the complete range of products under consideration is more distinctive and is, in accordance with the criteria detailed in the Document No. 07b - Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines less likely to give rise to an increased risk of a medication error. |
|  | **Sub-criterion (3)** **Supply route and associated cost****Only to be used in the circumstances described in paragraphs 12.2.1 (d)(ii) and 12.2.5** | The successful supplier’s distribution routes allow greater flexibility for ordering across a range of products |
|  | **Sub-criterion (4)** **“Extended Stability Data”****Assessed according to the requirements disclosed in:*** **Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements and Document No. 09 – Stability Data Requirements**

**QA assessments of the data provided that are confirmed by the evaluation panel as meeting the requirements will be deemed acceptable for award to the framework (subject to satisfying all other award criteria). QA review that are confirmed by the evaluation panel as not meeting the requirements will not be deemed acceptable for award to the framework unless there are no other qualifying offers where such Product will only be awarded to the framework in the absence of any other qualifying offers (and subject to satisfying all other award criteria).** | The successful supplier’s product evidenced protocols in accordance with the criteria detailed in Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements; and met the requirements outlined in Document No. 09 – Stability Data Requirements and therefore are appropriate for use in Participating Authorities in accordance with their current operational protocols and practices. |
|  | **Sub-criterion (5) “Additional Specification Requirements”****Assessed according to the requirements disclosed in:****Document No. 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements Appendix A (supplementary to general and regulatory)****Offers that are confirmed by the evaluation panel as meeting the requirements will be deemed acceptable for award to the framework (subject to satisfying all other award criteria). Offers that are confirmed by the evaluation panel as not meeting the requirements will not be deemed acceptable for award to the framework unless there are no other qualifying offers where such Product will only be awarded to the framework in the absence of any other qualifying offers (and subject to satisfying all other award criteria).** | The successful supplier’s product met the additional requirements as stated in Document No. 04b - Assessment Criteria, Stability Protocol and Additional Specification Requirements, Appendix A and therefore are appropriate for use in Participating Authorities in accordance with their current operational protocols and practices. |

*Table 1. Further description of award criteria requirements and standards*

12.2 **Award Methodology**

* + 1. **Identification of Lowest Priced Compliant Offer**

In respect of **each Product**, **for each Lot**, the evaluation shall comprise the following:

1. all (compliant) offers (for the Product) for that Lot will initially be ranked on Price against the price criteria (being Price sub-criterion (1) and, in respect of those Products listed in paragraph 12.1.4 only, Price sub-criterion (2) (the lowest price earning the highest rank). Such highest ranking offer (for the Product) for that Lot shall be the Lowest Priced Offer for the purposes of this paragraph 12.2.1.
2. the Lowest Priced Offer shall then be assessed against the requirements disclosed in the Assessment Criteria, Stability Protocol and Additional Specification Requirements (Document No.4b) and the quality criteria (being Quality sub-criterion (1) and (2)) according to the approach documented in Document No.4a 'Quality Assurance Process' and the ‘Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines’. A copy of this document is available at Document No. 07b. Where the Product does not comply with the requirements variously disclosed in these documents then the Product will not be deemed acceptable for award to a Framework Agreement and may be deemed invalid. Additionally, for the avoidance of doubt the requirements of Part A described in Document No. 04 ‘Quality Assurance Process’ specifically apply. Where the Product does not comply with the requirements disclosed in this document then the Product will not be deemed acceptable for award to a Framework Agreement and may be deemed invalid.
3. where the Lowest Priced Offer:
4. fulfils the quality award criteria (being Quality sub-criterion (1) and (2)), such offer (for the Product) for the Lot shall be the **Lowest Priced Compliant Offer** for the purposes of this paragraph 12.2;
5. fails to fulfil the quality award criteria (being Quality sub-criterion (1) and (2)), such offer shall be deemed non-compliant and shall be rejected. In such event, the process set out in paragraph 12.2.1(a) and (b) above shall be repeated (starting with the offer ranked second on Price) until an offer that fulfils the quality criteria is identified. Such offer shall be the **Lowest Priced Compliant Offer** for the purposes of this paragraph 12.2.

(d) where two or more offers are received at the same price and all such offers fulfil the quality award criteria (being Quality sub-criterion (1) and (2)) the following additional sub-criterion may be applied to differentiate between the offers and to identify the **Lowest Priced Compliant Offer**:

1. the cost of change sub-criterion described in Table 1 (Price sub-criterion (3)) at paragraph 12.1.5 above and paragraph 12.2.4 below shall be applied; and

(ii) if this does not differentiate between the offers, the supply route and associated cost sub-criterion described in Table 1 (Quality, sub-criterion (3)) at paragraph 12.1.5 above and paragraph 12.2.5 below shall be applied; and

* + 1. **In respect of each Product, the steps outlined in paragraph 12.2.1 (a) to (d) shall be repeated for each of the Lots being tendered (for the Product) in order to identify the Lowest Priced Compliant Offer for each such Lot.**
		2. **Awards**

For each Hospital Only and Hospital only (Housekeeping) Tender (CM/PHG/22/5657/02) and CM/PHG/22/5657/03), the Authority will identify the lowest cost solution for the Authority for all of the Lots being tendered. In respect of each Product, in furtherance of the lotting strategy described at paragraph 8.9, awards shall be made as follows:

1. **Where one Lot is being tendered (as specified in Documents No. 05a(i) or 05a(iii)).**

The Lot shall be awarded to the Lowest Priced Compliant Offer.

(b) **Where two Lots are being tendered (as specified in Document No. 05a(i) or 05a(v)):**

1. the Lot with the highest estimated volumes (anticipated for the duration of the agreement excluding any extension period) shall be awarded to the Lowest Priced Compliant Offer;
2. the Authority shall repeat the process described in paragraph 12.2.1 (a) to (d) to identify the offer ranked second. Such offer shall be the **Second Lowest Priced Compliant Offer** for the purposes of this paragraph 12.2.3;
3. where a Second Lowest Priced Compliant Offer is not identified, both of the Lots shall be awarded to the Lowest Priced Compliant Offer;
4. where a Second Lowest Priced Compliant Offer is identified, the Lot with the lowest estimated volumes (anticipated for the duration of the agreement excluding any extension period) shall be awarded to the Second Lowest Priced Compliant Offer.

The process described in paragraphs 12.2.1 to 12.2.3 above shall be repeated until at least one or more Offerors are successfully appointed to the framework agreement for each Product for all of the applicable Lots, or none of the offers are found to be acceptable against the award criteria.

(d) **Products listed at paragraph 12.1.4**

The processes described at paragraphs 12.2.1 to 12.2.2 shall apply to the Products listed at paragraph 12.1.4 save that they will apply to each combination of Products (as specified in paragraph 12.1.4), rather than the individual Products comprised in the combination.

* + 1. **Cost of change**

If the incumbent supplier (i.e. the supplier on the Framework Agreement immediately preceding that which is offered in this Invitation to Offer) and one or more other suppliers submit offers at exactly the same price, then subject to the award methodology and lotting strategy outlined at paragraph 12.2 and paragraph 8.9 above respectively the award shall be made to the incumbent supplier.

12.2.5 **Supply route and associated cost**

If the cost of change sub-criterion does not differentiate between the offers then supply routes shall be preferred in the following order and awards shall be made in this strict order of preference:

1. Combination of three or more wholesalers and direct distribution
2. Combination of two wholesalers and direct distribution

1. Combination of wholesaler and direct distribution
2. Three or more wholesalers

1. Two wholesalers
2. One wholesaler

1. Direct distribution only

Where subsequently the supply route and associated cost sub-criterion fails to differentiate the offers then the Authority will seek to award to the undifferentiated bids by appointing suppliers, at the Authority’s discretion, on a shared, sub-regional basis where possible.

12.2.6 For avoidance of doubt where all offers received are confirmed as “High Risk” by the evaluation panel, the award criteria shall be applied in the order of priority described in Table 1 above.

12.3**Evaluation Panel**

 Offers shall be evaluated by an evaluation panel against the award criteria. The evaluation panel may comprise members of the NHS England and NHS Improvement Commercial Medicines Unit, the Pharmaceutical Market Support Group, NHS Trust pharmacy procurement group representatives, NHS England commissioners and clinical experts.

12.4 **Final Decision to Award**

12.4.1 Following evaluation of Offers in accordance with the evaluation process set out in this Invitation to Offer, the Offeror who offers the most economically advantageous Offer shall be awarded the framework agreement for each Product in the relevant Lot(s).

12.4.2 The most economically advantageous tender for a particular Product in the relevant Lot shall be the Offer satisfying the award criteria and evaluation process set out in this Invitation to Offer.

12.4.3 Once the Authority has decided to make an award of a framework agreement the Authority will inform the successful Offeror, along with all other tenderers via the Atamis eTendering Portal of its intention to award a framework agreement and will allow a 10-day standstill period in accordance with Regulations 86 and 87 of the Public Contracts Regulations 2015.

12.4.4 Should the successful Offeror for a particular Product within a Lot decline to accept a framework agreement then, subject to the award methodology and lotting strategy outlined at paragraph 12.2 and paragraph 8.9 above respectively, it may be offered to the next ranked Offeror for that Product within the relevant Lot, until it has been accepted.

12.4.5 At any time following a standstill period of ten days, subject always to paragraph 10 above (and subject to there being no substantive challenge to that intention), a framework agreement shall be formally awarded, subject to contract, to the successful Offeror(s).

1. **E-auctions**

This tender will not include an electronic reverse auction stage.

1. **Contract monitoring**

The Authority is committed to helping improve the efficiency of contracted suppliers through sharing information on performance measurement. The criteria for measuring performance shall be agreed with the Successful Offerors and formally documented. It is possible that measurement criteria will develop during the term of the framework agreement - this will also be documented following agreement with the Successful Offerors.

1. **Costs and expenses**

The Authority will not be liable for any bid costs, expenditure, work or effort incurred by any Offeror in proceeding with or participating in this procurement, including if the procurement process is terminated or amended by the Authority.

1. **Amendments to Invitation to offer**

16.1 At any time prior to the closing time and date for the return of offers, the Authority may modify the documents comprising the Invitation to offer by notifying Offerors of the same in writing.

* 1. The Authority may extend the closing time and date for the return of offers to allow for significant amendments made by the Authority to be fully assessed and taken into account by Offerors.
1. **Procurement exercise timetable**

The following is the anticipated timetable for the procurement exercise and Offerors should note that these dates are indicative and are subject to change upon notice from the Authority. Offerors should also note and observe the timetable for the receipt of clarification queries under this procurement exercise as shown on the Atamis website.

|  |  |
| --- | --- |
| **Tender Stage** | **Estimated Date** |
| Tender Documents Returned to CMU via Atamis | Tuesday 18th October 2022 |
| Evaluation Period | 19th October 2022 to 31st November 2022  |
| Award notification issued to Offerors | Tuesday 1st December 2022 |
| Agreement Commences | 1st February 2023 |

**18. Continuity of Supply post-Award of Framework Agreements**

* 1. If the Framework Agreement is terminated, then the Authority may (at its option) re-tender the relevant Region or replace the Supplier with an alternative supplier without re-opening competition (and the limitations above on the number of Regions which an Offeror may be awarded shall not apply in this case). If the Authority chooses the latter option, the order of preference in which alternative suppliers will be invited to replace the Supplier will be as follows

18.1.1 where the Supplier being replaced submitted the Lowest-Priced Compliant Tender for the Region in question; the Offeror which submitted the second Lowest-Priced Compliant Tender for the Product for the Region in question; and then (if that Offeror does not accept the Authority's invitation) the other Offerors who submitted compliant tenders for the Region in question, in order of price (lowest first);

* + 1. where the Supplier being replaced did not submit the Lowest-Priced Compliant Tender for the Region in question; the Offeror which submitted the Lowest-Priced Compliant Tender for the Product for the Region in question and then (if that Offeror does not accept the Authority's invitation) the other Offerors who submitted compliant tenders for the Region in question, in order of price (lowest first);
		2. any other supplier of the Product to other Regions, in order of the Lowest-Priced Compliant Bid first; and
		3. any supplier which submitted a compliant tender for the Product but was not successful in being awarded any Region, in order of the Lowest-Priced Compliant Bid first.
	1. Where an alternative supplier is appointed by one of the means above, upon acceptance, such alternative supplier shall be appointed in place of the Supplier for the remainder of the Term of the Framework Agreement plus any extension of that Framework Agreement.
	2. By participating in this procurement process, Offerors acknowledge and agree that the processes set out in this section 18 and in the relevant provisions of the Framework Agreement referred to above are clear, precise and unequivocal review clauses which fully satisfy the requirements of Regulation 72(1)(a) of the Public Contracts Regulations 2015.
	3. Offerors should also note the contract terms contained within the Framework Agreement which are aimed at achieving continuity of supply and avoiding / minimising supply failures. In particular, these include:
		1. Clause 7 of Schedule 2 – Initial Stock Level and Contract Stock Level – condition precedent;
		2. Clause 8 of Schedule 2 – Stock Level Failure and Reporting;
		3. Clause 23 of Schedule 2 – Service Failures; and
		4. the Key Performance Indicators set out at Schedule 5 Part A of the Framework Agreement.

Should suppliers fail to meet the performance levels specified in the Framework Agreement then the sanctions specified in the Framework Agreement may apply. If the failure is such that one or more Warning Notices are issued, then in addition to the sanctions prescribed in Clause 24 of the Framework Agreement and in Schedule 5 Part A, the Authority may (in relation to future procurements) treat the issue of a Warning Notice as evidence of "*significant or persistent deficiencies by the* [supplier] *in the performance of a substantive requirement under a prior public contract*" for the purposes of Regulation 57(8) of the Public Contracts Regulations 2015. This means that the Authority may choose to exclude the supplier from that procurement in accordance with Regulation 57(8), subject to the supplier's ability to demonstrate "self-cleaning" in accordance with Regulation 57(13) to 57(17)(inclusive).