**Document No. 02**

**Project Title: NHS Framework Agreement for Aseptically Prepared Cytotoxic Medicines and Monoclonal Antibodies for the Treatment of Cancer commencing 1 April 2024 to 31 March 2028 (covering regions East of England, London, North of England and South East)**

**Tender Reference: CM/PHR/22/5686/01**

**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 Document No. 09.

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 Specification (Document No.04).

**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.

**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.

**8. Offer documentation and submission**

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

8.2 Each individual National Product Code (NPC) pack description is deemed to be a separate lot for the application of the award criteria.

* 1. Offers must comprise:
     1. the completed Response form on the Atamis website – found under “My Proposals and Quotes”;
     2. confirmation of acceptance of Document No. 04a – Conformance Specification (to be completed on the Atamis website);
     3. completion of Document No. 04b – Performance Specification;
     4. completion of Document No. 05 – Offer Schedule;
     5. confirmation of acceptance of Document No. 06 – Form of offer (to be completed on the Atamis website);
     6. completion of Document No. 07a – Aseptically Prepared Specials and Manufacturing Assessments;
     7. completion of Document No. 07b – Basket of Goods;
     8. completion of Document No. 08 - Confidential information schedule (if any types of information are considered to be confidential by the Offeror);
     9. a statement of prompt settlement discounts, if available;
     10. details of the Offeror’s ability, if any, to trade electronically;
     11. 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.
  2. The Form of offer must be approved via the Authority’s electronic tendering system by an officer duly authorised by the Offeror.
  3. The Form of Offer and other documents referred to in paragraph 8.2 above must be completed in full. Any offer may be rejected which –
     1. contains gaps, omissions or obvious errors; or
     2. is received after the closing time and date for the receipt of offers.
  4. 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
  5. 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.
  6. 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 1st December 2023.**

# **9.** **The Authority’s Rights**

9.1 The Authority reserves the right to:

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

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

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

9.1.4 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.

**10. Warnings and disclaimers**

10.1 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.

10.2 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.

10.3 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.

**11. Contract award criteria, scoring methodology and award threshold**

11.1 **Award Criteria**

11.1.1 Any framework agreement(s) awarded as a result of this procurement shall be awarded on the basis of the offer that is the most economically advantageous to the Authority (MEAT) in accordance with this Invitation to Offer. Where a framework agreement award is made, each Product within the Lot shall be awarded separately; each Product within the Lot will form a separate single supplier framework arrangement. The MEAT award criteria (described at paragraph 11.1.3 below) shall be applied in relation to each Product as outlined in this Invitation to Offer.

11.1.2 An award(s) shall be made in accordance with:

1. the award criteria described at paragraph 11.1.3 below;
2. the award methodology described at paragraph 11.2 below; and

on the basis of the lowest cost solution for the Authority for the Lot(s) 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.

11.1.3 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 change – **only to be used in the circumstances described in paragraphs 11.2.1 (d)(i) and 11.2.5**

(b) **Qualitative criteria of:**

1. sub-criterion (1) – QA assessment of risk to patient; and
2. sub-criterion (2) – Supply route and associated cost – **only to be used in the circumstances described in paragraphs 11.2.1 (d)(ii) and 11.2.6;**

Table1. Further description of award criteria and standards

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| --- | --- | --- |
| **Criteria** | **Sub-Criteria** | **Debrief Explanation** |
| **Price** | **Sub-criterion (1)**  Cost of product | The Successful Offeror's offer is the lowest-priced compliant offer received. |
| **Sub-criterion (2)**  Cost of change  **Only to be used in the circumstances described in paragraphs 11.2.1 (d)(i) and 11.2.5** | The Successful Offeror'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; and * the costs associated with explaining any differences between products to the patient, e.g. changes in pack presentation, excipients etc. |
| **Quality** – to include QA assessment of risk to **patient** | **Sub-criterion (1)**  Assessed according to the requirements disclosed in Document No. 07a – Aseptically Prepared Specials Manufacturing Assessments and Document No. 07b – Basket of Goods. | In accordance with the criterion as detailed in Document No. 07a – Aseptically Prepared Specials Manufacturing Assessments and Document No. 07b – Basket of Goods. |
| **Sub-criterion (2)**  Supply route and associated cost  **Only to be used in the circumstances described in paragraphs 11.2.1 (d)(ii) and 11.2.6** | The Successful Offeror's distribution routes allow greater flexibility for ordering across a range of products |

* 1. **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))
2. the Lowest Priced Offer will then be assessed against the quality criteria (being Document No. 07a – Aseptically Prepared Specials Manufacturing Assessments and Document No. 07b – Basket of Goods)
3. where the Lowest Priced Offer:
4. fulfils the Quality award criteria (being Document No. 07a – Aseptically Prepared Specials Manufacturing Assessments and Document No. 07b – Basket of Goods), such offer (for the Product) for the Lot shall be the **Lowest Priced Compliant Offer** for the purposes of this paragraph 11.2
5. fails to fulfil the Quality award criteria (being Document No. 07a – Aseptically Prepared Specials Manufacturing Assessments and Document No. 07b – Basket of Goods), such offer shall be deemed non-compliant and shall be rejected. In such event, the process set out in paragraph 11.2.1(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 11.2.

(d) where two or more offers are received at the same price and all such offers fulfil the quality award criteria (being Document No. 07a – Aseptically Prepared Specials Manufacturing Assessments and Document No. 07b – Basket of Goods) the following additional sub-criterion may be applied to differentiate between the offers and to identify the **Lowest Priced Compliant Offer**:

(i) the cost of change sub-criterion described in Table 1 (Price sub-criterion (3)) at paragraph 11.1.6 above and paragraph 11.2.5 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 11.1.6 above and paragraph 11.2.6 below shall be applied; and

* + 1. **In respect of each Product, the steps outlined in paragraph 11.2.1 (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 product, the Authority will identify the lowest cost solution for the Authority for all of the Lots being tendered.

* + 1. The process described in paragraphs 11.2.3 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.
    2. **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 outlined at paragraph 11.2 above the award shall be made to the incumbent supplier.

11.2.6 **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

11.2.7 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.

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

**11.4 Final Decision to Award**

11.4.1 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).

11.4.2 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.

11.4.3 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.

* + 1. Should the successful Offeror for a particular Product within a Lot decline to accept a framework agreement then, subject to the award methodology outlined at paragraph 12.2, it may be offered to the next ranked Offeror for that Product within the relevant Lot, until it has been accepted.
    2. At any time following a standstill period of ten days, subject always to section 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** 
   1. This tender will not include an electronic reverse auction stage.
2. **Contract monitoring**
   1. 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.
3. **Costs and expenses**
   1. 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.
4. **Amendments to Invitation to offer** 
   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.
   2. 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.
5. **Procurement exercise timetable**
   1. 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.

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| **Tender Stage** | **Date** |
| Tender Documents Returned to CMU via Atamis | 1 December 2023 |
| Evaluation Period | 11 December 2024 until 22 December 2024 |
| Award notification issued to Offerors | 2 February 2024 |
| Agreement Commences | 1 April 2024 |

1. **Continuity of Supply post-Award of Framework Agreements**
   1. If the Framework Agreement is terminated, then the Authority may (at its option) re-tender or replace the Supplier with an alternative supplier without re-opening competition. 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:
      1. the Offeror which submitted the second Lowest-Priced Compliant Tender for the Product; and then (if that Offeror does not accept the Authority's invitation) the other Offerors who submitted compliant tenders, in order of price (lowest first);
      2. Where an alternative supplier is appointed, 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.