**Document No. 02**

**Invitation to offer for NHS National Framework Agreement for the Supply of Generic Pharmaceuticals – Wave 12**

**Offer reference number: CM/PHG/17/5531**

**Period of framework agreement: The total maximum duration of the framework agreement to be no more than 48 months (24 months plus options to extend (at the Authority's sole discretion) for up to a further 24 months)**

**Oral Products: All regions 01/02/2020 to 28/02/2021 (13 months)**

**Hospital Only Products: DLS/DNE/DNW 01/02/2020 to 31/01/2022 (24 months)**

 **DLN/DCE/DSW 01/02/2020 to 31/01/2021 (12 months)**

**Terms of offer**

1. **The Authority and Participating Authorities**
	1. The NHS Commissioning Board, operating under the name of NHS England ("Authority") is conducting this procurement exercise as a central purchasing body for and on behalf of the organisations specified in Schedule 8 of Document No. 03 (Framework Agreement and Terms and Conditions) ("Participating Authorities"), to establish a framework agreement ("Framework Agreement") with the successful Offerors. Participating Authorities will enter into contracts under the Framework Agreement for the supply of the goods and/or services.
	2. The Authority will not be a party to any such subsequent contracts. 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 fulfilling the requirements imposed by Part 2 of the Public Contracts Regulations 2015, so far as applicable, when conducting an award of contract(s) under the Framework Agreement.
	3. The Authority is not responsible or accountable for and shall have no liability whatsoever in relation to:
		1. the conduct of Participating Authorities in relation to the Framework Agreement;
		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
		3. the performance or non-performance of a contract between the successful Offeror and the Participating Authority entered into pursuant to the Framework Agreement.
	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**
	1. This procurement exercise concerns the conclusion 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. The Authority cannot mandate the Participating Authorities 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.
	3. Any volume estimates provided to Offerors by Authority staff 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.
	4. By submitting an Offer, an Offeror is deemed to acknowledge and agree that:
		1. the supply of goods and/or services under any Framework Agreement resulting from this procurement exercise is not an exclusive arrangement; and
		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**
	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, unless such information has been supplied fraudulently by the Authority.
	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.
	3. 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.
	4. For these purposes, the Authority may disclose within Government any of the Offerors' documentation/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 unless pursuant to any applicable legal obligation (see Section 4: Freedom of Information Act 2000, below).
	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**
	1. The Freedom of Information Act 2000 ("FOIA") applies to the Authority.
	2. Offerors should be aware of the Authority’s obligations and responsibilities under 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 FOIA applies. The Authority may also include certain information in the NHS England Freedom of Information Publication Scheme (<https://www.england.nhs.uk/contact-us/pub-scheme/>).
	3. In certain circumstances, and in accordance with the Code of Practice issued under section 45 of FOIA 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 FOIA, the Authority must comply with a strict timetable and the Authority would, therefore, expect a timely response to any such consultation within five (5) working days (a working day being any day of the week from Monday to Friday excluding Bank Holidays in England).
	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 or which would be damaging to the Offeror's commercial interests if disclosed ("commercially sensitive") and which an Offeror wishes not to be disclosed, then Offerors must clearly identify in their offer documentation the information to which Offerors consider those exceptions under FOIA apply. Offerors must give a clear indication which material is to be considered confidential or commercially sensitive and why it is considered to be so, along with the time period for which it will remain confidential or commercially sensitive. Such indications by Offerors must 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 how they have determined that the result of the public interest test applicable under FOIA (where applicable) would 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 not be accepted. 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 or commercially sensitive, the Authority may be required to disclose it under FOIA if a request is received.
	5. The Authority cannot accept that trivial information or information which by its very nature cannot be regarded as confidential or commercially sensitive should be subject to any obligation of confidence.
	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.
	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**
	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 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 set out 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>

* 1. 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 FOIA.
1. **Samples**
	1. Offerors will be required to submit samples of each item offered. Such samples shall be provided free of charge.
	2. Samples should be despatched under separate cover as and when required by the Authority.
	3. Samples should be clearly marked with the name of the Offeror and the project code reference: **CM/PHG/17/5531.** Samples should be clearly labelled "NHS **National Framework Agreement for the Supply of Generic Pharmaceuticals – Wave 12** "**.**
2. **Prices**
	1. Prices must be stated in the offer schedules, and must remain open for acceptance until one hundred and twenty (120)days from the closing date for the receipt of offers.
	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.
	3. Prices must be quoted in sterling (GBP) and exclusive of Value Added Tax.
3. **Requirement and Lot Structure**
	1. This procurement concerns the purchasing of generic products ("Products"). The Products are separated into Hospital Only Products and Oral Products.
	2. For the Oral Products (CM/PHG/17/5531/01) three Regions are being tendered (see Table 1 below).

**Table 1**

|  |  |
| --- | --- |
| **Lot** | **Regions** |
| Lot 1 – Oral Products (CM/PHG/17/5531/01) | CESWLSNENWLN |

* 1. For the Hospital Only Products (CM/PHG/17/5531/02) six Regions are being tendered and have been divided into two Lots (see Table 2 below) where each Region within a Lot is deemed to be a separate entity. On that basis an Offeror may be awarded one or more Regions within each Lot (refer to clause 8.10.2 below for further explanation)

**Table 2**

|  |  |
| --- | --- |
| **Lot** | **Regions** |
| Lot 1 – Hospital Only Products (CM/PHG/17/5531/02) |  DLSDNEDNW |
| Lot 2 Hospital Only Products (CM/PHG/17/5531/02) |  DLNDCEDSW |

* 1. 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).
	2. A detailed description of the goods and/or services that an Offeror will be required to supply for a Region in which it has been successful is set out in the offer schedules and the Specification (Document No. 04).
	3. Each National Product Code product description (as listed in the relevant offer schedules) shall constitute a Product for the purposes of this Invitation to Offer.
	4. The tender comprises the following offer schedules:
		1. **CM/PHG/17/5531/01 (Document No. 05a(i)) – Oral Products:**

For each Product comprised in this offer schedule, Document No. 5a(i) specifies the Regions 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 2 above.** 

**In this example each buying group is a Region (total of 3 Regions). The numbers 1-3 in the boxes above do not relate to specific Regions but to the number of Regions that an Offeror may tender for in respect of this product. Please refer to paragraph 8.9 regarding offer prices.**

* + 1. **CM/PHG/17/5531/02 (Document No. 05a(iii)) – Hospital Only Products:**

For each Product comprised in this offer schedule, Document No. 5a(iii) specifies the Regions 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 2 above.** 

**In this example each buying group within the Lot is a Region (total of 3 separate Regions). The numbers 1-3 in the boxes above do not relate to specific Regions but to the number of Regions that an Offeror may tender for in respect of this product per Lot. Please refer to paragraph 8.9 regarding offer prices.**

* 1. Offerors may submit tenders for all (or any) of the Regions specified in the offer schedules. If you intend only to bid for certain Regions or a single Lot, you **must** specify this clearly in your tender and state which Regions (or Lot) you are tendering for. Your tender will then only be evaluated in respect of those Regions or that Lot.
	2. One price must be submitted for **all Regions (per Product)** being offered within Lot 1 and Lot 2 of the Hospital Only tender but the offered price for Lot 1 does not have to be the same as the offered price submitted for Lot 2. One price must be submitted for all Regions (per Product) being offered within the Oral Products tender.
	3. To ensure a diverse range of suppliers, the Authority may limit the number of Regions that may be awarded to one Offeror as follows:
		1. In respect of each Product listed in the Oral Products tender (CM/PHG/17/5531/01) offer schedule, up to all of the Regions being tendered (for the Product) as specified in Document No. 05a(i) may be awarded to one Offeror (regardless of the number of Offers received).
		2. In respect of each Product listed in each Lot of the CM/PHG/17/5531/02 – Hospital only products offer schedule, awards will be limited as follows –
			+ 1. where Document No. 05a(iii) specifies that all three Regions in a Lot are being tendered, the following restrictions shall apply, subject to paragraph 12.2.2:
1. where three or more compliant offers that meet the qualitative criteria (and, as more particularly described in paragraph 12.2.2, the second and third ranked offers do not exceed 125% of the median of compliant offered prices) are received, a maximum of one Region for the Lot may be awarded to one Offeror;
2. where only two compliant offers that meet the award criteria (and, as more particularly described in paragraph 12.2.2, the second ranked offer does not exceed 125% of the of the median of compliant offered prices) are received, a maximum of two Regions for the Lot may be awarded to one Offeror;
3. where only one compliant offer that meets the qualitative criteria is received, all three Regions for the Lot may be awarded to one Offeror.
4. where Document No. 05a(iii) specifies that two Regions in a Lot are being tendered, the following restrictions shall apply, subject to paragraph 12.2.2:

(i) where two or more compliant offers that meet the qualitative criteria (and, as more particularly described in paragraph 12.2.2, the second offer does not exceed 125% of the median of compliant offered prices) are received, a maximum of one Region for the Lot may be awarded to one Offeror;

1. where only one compliant offer that meets the qualitative criteria is received, both Regions for the Lot may be awarded to one Offeror.
	1. . In respect of each Product in each Region, one Framework Agreement will be awarded to a single supplier for **each** Region.
2. **Tender documentation and submission**
	1. Offers may be submitted for all goods and/or services or for selected items.
	2. The goods and/or services offered by Offerors must be strictly in accordance with the Specification (Document No. 04). 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.
	3. CMU’s Selectt programme must be used by Offerors to create the tender 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. Tenders **must** comprise:
		1. the completed Response form on the BravoSolution website – found under “My Response”;
		2. the offer schedules in .cmu format - Document No. 05a(ii), and 05a (iv) of the tender pack, Selectt bid file(s), with the title:

CM\_PHG\_17\_5531\_01\_xxx.cmu

CM\_PHG\_17\_5531\_02\_xxx.cmu

where xxx represents your organisation's tendering supplier code;

* + 1. the Form of Offer (Document No. 06) to be completed on the Bravo website;
		2. the Quality Control technical sheet (Document No. 07a) to be completed on the Bravo website;
		3. the Confidential Information Schedule (Document No. 08), if any types of information are considered to be confidential by the Offeror;
		4. the Required Stability Information (Document No. 09 Stability data requirements) and appropriate supporting documentation where applicable;
		5. a statement of prompt settlement discounts, if available;
		6. details of the Offeror’s ability, if any, to trade electronically; and
		7. confirmation that any information previously supplied to the Authority in connection with the tender is still accurate and is incorporated by reference into the tender.
	1. The Form of Offer must be approved via the Authority’s electronic tendering system by an officer 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 tender 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 tenders.
		3. For clarification about completing the tender documentation, commercial and / or technical queries please send a message via the Bravosolution messaging portal:

[https://nhsengland.bravosolution.co.uk/web/login.shtml](https://cmu.bravosolution.co.uk/web/login.shtml)

* 1. 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 sensitive, 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 sensitive. 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.
	2. Tenders and all documents relating to the tenders must be written in English and submitted to the Authority via the Authority’s electronic tendering system by **13:00 on 18th June 2019**.
1. **Authority’s Rights**
	1. The Authority reserves the right to:
		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;
		2. seek clarification (including further information or documents) in respect of an Offeror's submission;
		3. disqualify any Offeror that does not submit a compliant tender in accordance with the instructions in this Invitation to Offer;
		4. disqualify any Offeror that is guilty of serious misrepresentation in relation to its tender or the procurement process;
		5. withdraw this Invitation to Offer at any time, or re-invite tenders on the same or any alternative basis;
		6. accept a tender either in whole or in part, each item being for this purpose treated as tendered separately;
		7. choose not to award any Framework Agreement as a result of the procurement process for any reason;
		8. 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
		9. at any time terminate the procurement process for any reason.
	2. For the avoidance of doubt, the Authority will not be liable to any Offeror for its costs of participating in this tender process in any of the circumstances listed in paragraph 10.1 above, or in any other circumstances.
2. **Warnings and disclaimers**
	1. While the information contained in this Invitation to Offer is believed to be correct at the time of issue, neither the Authority, its advisors, nor any other awarding authorities give any warranty (express or implied), make any representation or accept any liability (whether in contract, quasi- or implied contract, tort (including negligence), misrepresentation, breach of statutory duty, judicial review or other public law cause of action, restitution, legitimate expectation or any equitable cause of action, or any other cause of action whatsoever) in respect of its accuracy, adequacy or completeness. 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 fraud or fraudulent misrepresentation made by or on behalf of the Authority.
	2. If an Offeror proposes to enter into a Framework Agreement with the Authority, it must rely solely 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 such agreement.
	3. Neither the issue of this Invitation to Offer, nor any of the information presented in it, should be regarded as a commitment or representation on the part of the Authority (or any other person) to enter into a contractual arrangement.
3. **Contract award criteria and award methodology**
	1. **Award Criteria**
		1. Any Framework Agreement(s) awarded as a result of this procurement shall be awarded on the basis of the tender that is the lowest priced against the Price Criterion and which satisfies the Quality Criteria, each as set out in paragraph 12.1.7 and Table 1 below. 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 agreement.
		2. With the exception of those Products listed at Paragraphs 12.1.4, 12.1.5 and 12.1.6 below, the Award Criteria (as described in paragraph 12.1.7 and Table 1 below) will be applied in relation to each of the Oral Products and separately in relation to Lots 1 and 2 for the Hospital Only Products, .
		3. Any award(s) will be made in accordance with:
			1. the award criteria described at paragraph 12.1.7 below;
			2. the award methodology described at paragraph 12.2 below; and
			3. the lotting strategy described at paragraph 8.10 above.
		4. For the following Products, where the NHS requires the different strengths to be mixed (and product liability issues would be complicated by awards to differing Offerors), the Product descriptions shall be combined:

|  |
| --- |
| **Bendamustine Solution for Infusion**Bendamustine Powder For Solution For Infusion Vial 100mg |
| Bendamustine 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 Injection 1000mg |
| Dacarbazine Injection 100mg |
| Dacarbazine Injection 200mg |
| Dacarbazine Injection 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 Solution For Injection** |
| Doxorubicin Solution For Injection Vial 10mg/5ml |
| Doxorubicin Solution For Injection Vial 50mg/25ml |
| **Epirubicin Solution For Injection** |
| Epirubicin Solution For Injection Vial 10mg/5ml |
| Epirubicin Solution For Injection Vial 50mg/25ml |
| **Etoposide Solution For Infusion** |
| Etoposide Injection Vial 20mg/ml 5ml |
| Etoposide Solution For Injection Vial 500mg/25ml |
| **Fluorouracil Solution For Infusion (50mg/ml 5%)** |
| Fluorouracil Solution For Infusion Vial (5%) 2.5g/50ml |
| Fluorouracil Solution For Infusion Vial (5%) 500mg/10ml |
| Fluorouracil Solution For Infusion Vial (5%) 5G/100ml |
| **Gemcitabine Concentrate For Solution For Infusion** |
| Gemcitabine Concentrate For Solution For Infusion Vial 1g |
| Gemcitabine Concentrate For Solution For Infusion Vial 200mg |
| Gemcitabine Concentrate For Solution For Infusion Vial 2g |
| **Gemcitabine Powder For Solution For Infusion** |
| Gemcitabine Powder For Solution For Infusion Vial 1g |
| Gemcitabine Powder For Solution For Infusion Vial 200mg |
| **Ifosfamide Injection** |
| Ifosfamide Injection 1g |
| Ifosfamide Injection 2g |
| Ifosfamide Injection 500mg |
| **Irinotecan Solution For Infusion** |
| Irinotecan Solution For Infusion Vial 100mg/5ml |
| Irinotecan Solution For Infusion Vial 300mg/15ml |
| Irinotecan Solution For Infusion Vial 40mg/2ml |
| **Methotrexate Solution For Injection (25mg/ml**) |
| Methotrexate Solution For Injection Vial 500mg/20ml |
| Methotrexate Solution For Injection Vial 50mg/2ml |
| **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 150mg/25ml |
| Paclitaxel Solution For Infusion Vial 300mg/50ml |
| Paclitaxel Solution For Infusion Vial 30mg/5ml |
| **Vincristine Solution For Injection** |
| Vincristine Solution For Injection Vial 1mg/1ml |
| Vincristine Solution For Injection Vial 2mg/2ml |
| **Vinorelbine Solution For Injection** |
| Vinorelbine Solution For Injection Vial 10mg/1ml |
| Vinorelbine Solution For Injection Vial 50mg/5ml |

* + - 1. The NHS has a requirement for a number of tendered products listed at Appendix 1 of this document to have a minimum extended stability, where available. The products above are all included within Document No. 9 – Stability data requirements. Any Offeror submitting an Offer for any Product listed in Document No. 09 – Stability data requirements MUST fully complete the required information requested in Document No. 09 – Stability data requirements for the relevant products and return the completed Document No. 09 – Stability data requirements as part of their Offer. Failure to fully provide this information may invalidate Offerors' submissions for these products.
			2. In respect of the above-named Products, 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 (International Non-proprietary Name (INN)) and awards shall be made in accordance with:
				1. the award criteria described at paragraph 12.1.7 below;

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

(d) the lotting strategy described at paragraph 8.10 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 incorporated into the INN by multiplying the offer prices tendered by the Offeror (for each Product incorporated into the INN) by the estimated volumes for the Lot (anticipated for the duration of the agreement excluding any extension period) for the respective Products incorporated into the INN).

* + - 1. In respect of the above-named Products, where no compliant offers are received which meet, as a minimum, the extended stability requirements shown in Document No. 09 – Stability data requirements, all Regions within 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 12.1.7 below) shall be applied in relation to the molecule/form (International Non-proprietary Name (INN)) and awards shall be made in accordance with:
				1. the award criteria described at paragraph 12.1.7 below;

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

(d) the lotting strategy described at paragraph 8.10 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 incorporated into the INN by multiplying the offer prices tendered by the Offeror (for each Product incorporated into the INN) by the estimated volumes for the Lot (anticipated for the duration of the agreement excluding any extension period) for the respective Products incorporated into the INN).

* + - 1. In respect of those products **NOT** shown 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 12.1.7 below;

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

(d) the lotting strategy described at paragraph 8.10 above,

* + - 1. In respect of those products **NOT** shown 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, all Regions within 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 12.1.7 below;

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

(d) the lotting strategy described at paragraph 8.10 above.

* + 1. For the following cytotoxic products the NHS requires the product awarded to be in a blister pack presentation:

Cyclophosphamide Tablets 50mg

Imatinib (Glivec or Eq) Tablets/Capsules 100mg

Imatinib (Glivec or EQ) Tablets/Capsules 400mg

Imatinib Orodispersible Tablets 100mg

Imatinib Orodispersible Tablets 400mg

Imatinib Tablets/Capsules 100mg

Imatinib Tablets/Capsules 300mg

Imatinib Tablets/Capsules 400mg

Ivabradine Tablets 5mg

Ivabradine Tablets 7.5mg

* + - 1. Awards for these products will be made, where possible, to offers for blister packs (subject to the offers meeting all other award criteria stated in paragraph 12.1.7 of this document), where cheaper offers are received that are not in a blister pack the offer for the product not in a blister pack will be deemed to be non-compliant.
			2. Products that are not in a blister pack will only be awarded to the framework agreement in the absence of any other offers meeting this criterion (and subject to the offer meeting all other award criteria stated in paragraph 12.1.7 of this document).
		1. Notwithstanding the requirements in Document No. 09 – Stability data requirements, for the following products the NHS requires the products awarded to be contained in primary packaging designed to protect the product from light:

Ciprofloxacin solution for infusion 100mg/50ml

Ciprofloxacin solution for infusion 200mg/100ml

Ciprofloxacin solution for infusion 400mg/200ml

* + - 1. Awards for these products will be made to offers for products in light-protected primary packaging (subject to the offers meeting all other award criteria stated in paragraph 12.1.6 of this document), where cheaper offers are received for products that are not in light-protected primary packaging the offer for the product not in light-protected primary packaging will be deemed to be non-compliant.
			2. Products that are not in light-protected primary packaging will only be awarded to the framework agreement in the absence of any other offers meeting this criterion (and subject to the offer meeting all other award criteria stated in paragraph 12.1.7 of this document).
		1. For each Product, the award criteria are as follows:

 (a) **Price criteria of:**

(i) sub-criterion (1) - Cost of product;

(ii) 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;
2. sub-criterion (2) – QC 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**.

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| **Criteria** | **Sub-Criteria** | **Debrief Explanation** |
| **Price** | **Sub-criterion (1)**Cost of product | The successful Offeror’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) and 12.2.4** | The successful sOfferor’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 approach documented in the "Guidance for performing a pharmaceutical quality assessment of licensed medicines for the NHS". A copy of this document is available at Document No. 7b. Product QC 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” 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 is in accordance with the criteria detailed in the "Guidance for performing a pharmaceutical quality assessment of licensed medicines for the NHS” and therefore less likely to give rise to an increased risk of a medication error and the PQA assessment for their product reflects this. |
| **Sub-criterion (2)**Assessed according to the approach documented in “Guidance for performing a pharmaceutical quality assessment of licensed medicines for the NHS”. A copy of this document is available at Document No.07b within the Invitation to Offer pack – [Range issue where the Authority is splitting an award across a range of products for differentiation reasons]. | 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 “Guidance for performing a pharmaceutical quality assessment of licensed medicines for the NHS”, 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 Offeror’s distribution routes allow greater flexibility for ordering across a range of products |

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

* 1. **Award Methodology**

**Identification of Lowest Priced Compliant Tender**

* + 1. The evaluation will comprise the following for each Product for each Lot and each Region:
1. tenders will initially be ranked on price against the Price Criterion (being sub-criteria (1) and (2)) and – in respect of those Products listed in paragraph 12.1.4 only – sub-criterion (2)) (the lowest price earning the highest rank). Such highest ranking tender shall be the Lowest Priced Tender;
2. the Lowest Priced Tender will then be assessed against the Quality Criteria (being Quality Sub-criteria (1) and (2)) according to the approach documented in the "Guidance for performing a pharmaceutical quality assessment of licensed medicines for the NHS". A copy of this document is available at Document No. 07b;
3. where the Lowest Priced Tender:
4. fulfils the Quality Criteria, that tender will be the **Lowest Priced Compliant Tender** for the relevant Region;
5. fails to fulfil the Quality Criteria, the tender will be **rejected**. In that event, the process set out in paragraphs 12.2.1(a) and (b) above will be repeated (starting with the tender ranked second on Price) until a tender that fulfils the Quality Criteria is identified. Such tender shall be the **Lowest Priced Compliant Tender** for the relevant Region;
6. where two or more tenders are received at the same price in respect of a single Region and all such tenders 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**:

(i) the cost of change sub-criterion described in Table 1 (Price sub-criterion (3)) at paragraph 12.1.7 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 12.1.7 above and paragraph 12.2.5 below shall be applied; and

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

* + 1. **Awards**

**Hospital Only Products (CM/PHG/17/5531/02)Lots 1 and 2**

* + - 1. In respect of Hospital Only Products (CM/PHG/17/5531/02) - Lots 1 and 2, Offerors may not be awarded more than one Region within the same Lot, nor more than two Regions overall, unless a compliant tender from a different Offeror is not submitted for each of the three Regions within either or both Lots, in which case the Regions will be awarded in accordance with paragraph 12.2.2.1(a) – (c) below.

For each Product, the Authority will identify within each Lot the lowest cost solution for the Authority for all of the Regions being tendered. In respect of each Product, in furtherance of the lotting strategy described at paragraph 8.10, awards shall be made as follows:

1. **Where one Region is being tendered within the Lot (as specified in Document No. 05a(i) and/or Document No. 05a(iii)):**

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

(b) **Where two Regions are being tendered within the Lot (as specified in Document No. 05a(i) and/or Document No. 05a(iii)):**

1. the Region 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 12.2.2;
3. where a Second Lowest Priced Compliant Offer is not identified, both of the Regions shall be awarded to the Lowest Priced Compliant Offer;
4. where the Second Lowest Priced Compliant Offer is greater than 125% of the median of compliant offered prices, both of the Regions shall be awarded to the Lowest Priced Compliant Offer; and
5. where the Second Lowest Priced Compliant Offer is less than 125% of the median of compliant offered prices, the Region 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.

(c) **Where three Regions are being tendered within the Lot (as specified in Document No. 05a(i) and/or Document No. 05a(iii)):**

1. the Region 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 12.2.2;
3. the Authority shall repeat the process described in paragraph 12.2.1 (a) to (d) to identify the offer ranked third. Such offer shall be the **Third Lowest Priced Compliant Offer** for the purposes of this paragraph 12.2.2;
4. where both a Second Lowest Priced Compliant Offer and a Third Lowest Priced Compliant are not identified, all three Regions shall be awarded to the Lowest Priced Compliant Offer;
5. where the Second Lowest Priced Compliant Offer is greater than 125% of the median of compliant offered prices, all three Regions shall be awarded to the Lowest Priced Compliant Offer;
6. where a Second Lowest Priced Compliant Offer that is less than 125% of the median of compliant offered prices is identified but a Third Lowest Priced Compliant Offer is not identified:
7. the Region with the second highest estimated volumes (anticipated for the duration of the agreement excluding any extension period) shall be awarded to the Lowest Priced Compliant Offer; and
8. the Region 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;
9. where the Third Lowest Priced Compliant Offer is greater than 125% of the median of the compliant offered prices:
10. the Region with the second highest estimated volumes (anticipated for the duration of the agreement excluding any extension period) shall be awarded to the Lowest Priced Compliant Offer; and
11. the Region 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;
12. where the Third Lowest Priced Compliant Offer is less than 125% of the median of compliant offered prices:
13. the Region with the second highest estimated volumes (anticipated for the duration of the agreement excluding any extension period) shall be awarded to the Second Lowest Priced Compliant Offer; and
14. the Region with the lowest estimated volumes (anticipated for the duration of the agreement excluding any extension period) shall be awarded to the Third Lowest Priced Compliant Offer.

(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. The process described in paragraphs 12.2.1 to 12.2.2 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 Offerors submit offers at exactly the same price, then subject to the award methodology and lotting strategy outlined at paragraph 12.2 and paragraph 8.10 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

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.

* 1. **Evaluation Panel**
		1. Tenders 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.
	2. **Final Decision to Award**
		1. Following evaluation of tenders in accordance with the evaluation process set out in this Invitation to Offer, the Offerors who submit the most economically advantageous tenders shall be awarded Framework Agreements for the relevant Region(s) and/or Lot(s).
		2. 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 bravosolutions eTendering Portal of its intention to award the Framework Agreements.
		3. 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 above, it may be offered to the next ranked Offeror for that Product within the relevant Region or Lot, until it has been accepted.
		4. A 10-day standstill period will follow the announcement by the Authority in accordance with paragraph 12.4.3. The standstill period will commence at midnight at the end of the date on which the Authority makes the announcement under paragraph 12.4.3 above, and will end at midnight at the end of the tenth day following that date, unless the tenth day is not a working day, in which case the standstill period will end at midnight at the end of the next working day. At any time following the standstill period, subject always to paragraph 10 above (and subject to there being no substantive challenge to that intention), the Framework Agreements may be entered into between the Authority and the successful Offeror(s).
1. **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 selected 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 Offerors.
2. **Costs and expenses**
	1. The Authority will not be liable for any bid costs, expenditure, work or effort incurred by an Offeror in proceeding with or participating in this procurement, including if the procurement process is terminated or amended by the Authority.
3. **Amendments to Invitation to Offer**
	1. At any time prior to the closing time and date for the return of tenders, 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 tenders to allow for significant amendments made by the Authority to be fully assessed and taken into account by Offerors.
4. **Procurement exercise timetable**
	1. The following is the timetable for the procurement exercise and Offerors shall 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 Bravo website.

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| **Tender Stage** | **Date** |
| Tender Documents Returned to CMU via Bravo | 13:00 hours 18th June 2019 |
| Evaluation Period | 19th June 2019 to 30th September 2019 |
| Award notification issued to Offerors | 1st October 2019 |
| Agreement Commences | 1st February 2020 |

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 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
		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);
		2. 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);
		3. any other supplier of the Product to other Regions, in order of the Lowest-Priced Compliant Bid first; and
		4. 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.
	2. 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.
	3. By participating in this procurement process, Offerors acknowledge and agree that the processes set out in this section 17 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.
	4. 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 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 Schedule 5 Part A, 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 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).