Attachment 7 – Award Questionnaire

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Introduction

You must complete the Award Questionnaire’ (AQ1 to AQ11) and all the relevant Appendices contained in this document and submit using the Department’s e-Sourcing portal.

The evaluation will be carried out using your responses to this Questionnaire using the award criteria, guidance and scoring matrix set out in ‘Attachment 5 - Evaluation Guidance’*.*

Annex A - Award Questionnaire

Award questions

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| --- | --- | --- | --- | --- | --- |
| **Question** | **AQ1** | **Weight** | **[N/A]** | **Word Limit** | 400 |
| **Subject** | Overview - This response is not scored - it is only intended to give the Authority an overview of the tenderers ability. |
| **Question** | Tenderers must provide your understanding of the QP Pharmacovigilance role in the context of this ITT |
| **Response Guidance**  | Tenderers must provide a concise summary highlighting the key aspects of the proposal.This should include a brief overview of how the tenderer will support the Authority in meeting its objectives as the MAH for Healthy Start Vitamins. |

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| ****Potential Provider Response / Additional commentary**** |
| Click here to enter text.  |

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| **Question** | **AQ2** | **Weight** | **15** | **Word Limit** | **[**400 |
| **Subject** | QP Services |
| **Question** | Tenderers must provide information regarding the provision of QP services on a 24 hour per day, year round basis. |
| **Response Guidance**  | The Authority seeks to establish how the Tenderer intends to meet the requirements of the legislation for the MAH to have access to a QP services on a 24 / 7 basis, with these services provided by appropriately qualified personnel.The Tenderer’s response should show that it:1. Understands the legislative requirements as to the provision of QP Services;
2. Has access to appropriately qualified personnel to provide QP Services, and the response gives details of personnel, their qualifications and experience;
3. That it has systems in place to ensure that QP Services can be provided on a 24 hour, year-round basis.
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ3** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Reporting Systems and procedures |
| **Question** | Tenderers must provide details on how they would handle reports of adverse reactions and / or incidents. |
| **Response Guidance**  | The Authority seeks to establish that the Tenderer has processes in place to handle adverse reactions and / or incidents.The Tenderer’s response shows that it has:1. A credible and robust electronic system for recording adverse reactions and incidents;
2. Has processes for investigating adverse reactions and / or incidents;
3. Has processes for reporting adverse reactions and / or incidents to the relevant Regulatory Authorities within the timescales set out in the legislation, and to the Authority;
4. Has a process in place to undertake any follow-up action which may be required.
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ4** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Signal Detection Activity |
| **Question** | The Tenderer must provide information on signal detection activity |
| **Response Guidance**  | Seeks to establish that the Tenderer has the necessary processes in place to undertake signal detection activity and to respond to the results of this activityThe Tenderer’s response should give details of:- the frequency of the signal detection activity it proposes to carry out- the frequency of detection activity, and the sources of information it will use for this activity1. - how information from signal detection activity will be recorded, analysed and used to prepare the extended signal detection report,
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ5** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Regulatory Authority interaction |
| **Question** | The Tenderer must provide an outline report on how they would respond to any enquiries from the Regulatory Authorities. |
| **Response Guidance**  | The Authority seeks to establish that the Tenderer is able to respond to any queries about the product for the Regulatory Authorities.The Tenderer’s response shows that it:1. Has a process in place to receive, to analyse and to respond to any queries from the Regulatory Authorities within the timescales set out in the legislation?
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ6** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Pharmacovigilance System Master File (PSMF) maintenance |
| **Question** | The Tender must provide information on how they intend to ensure that the Pharmacovigilance System Master File (PSMF) is kept up to date in accordance with legislation. |
| **Response Guidance**  | The Authority seeks to establish that the Tenderer has governance procedures in place that ensures the PSMF is kept up to date.The Tenderer’s response shows that it:1. Has a system on which the PSMF can be held.
2. Has a documented governance procedure in place that ensures that the PSMF is kept up to date in line with the requirements of legislation.
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| ****Potential Provider Response / Additional commentary**** |
| Click here to enter text.  |

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| **Question** | **AQ7** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Maintenance procedures of Summary of Product Characteristic’s (SPC), Patient Information Leaflets (PIL’s) and other information |
| **Question** | The Tenderer must provide information on how they would update the SPC’s, PIL’s and labelling including the provision of summary documents to support variation applications to MHRA, as necessary. |
| **Response Guidance**  | The Authority seeks to establish that the Tenderer has the necessary internal processes to successfully deliver the specification.The Tenderer’s response shows that it:1. Has processes in place to conduct any necessary updating of the Summary of Product Characteristics (SPC’s), Patient Information Leaflets (PIL’s), and labelling including the provision of summary documents to support variation applications to MHRA.
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ8** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Collaboration with Authority and its representatives |
| **Question** | The Tenderer must outline how they intend to work together with the Authority, the Authority’s Contract Manager, and the product manufacturer in an effective and collaborative manner. |
| **Response Guidance**  | The Authority seeks to establish that the Tenderer has the capability to build effective working relationships with key stakeholders to ensure that a high-quality and compliant vitamin product is provided to Healthy Start beneficiaries.The Tenderer’s response shows that it:1. Is able to build an effective working relationship with the Authority and the Authority’s Contract Manager;
2. Is able to work with the product manufacturer, providing input on QP and other quality issues as necessary.
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ9** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Exit Strategy |
| **Question** | The Authority requests that the bidder submits a suitable Exit Strategy. |
| **Response Guidance**  | The Authority seeks to establish that the Tenderer has a creditable Exit Strategy which will support the Authority’s re-procurement of the QP service at the end of the current contract.The Tenderer’s response show that it:1. Has a developed and creditable Exit Strategy which will allow the Authority to successfully re-procure the QP service at the end of this contract.
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ10** | **Weight** | **10** | **Word Limit** | 400 |
| **Subject** | Submission of Business Continuity and Disaster Recovery Plans (BCDR) |
| **Question** | The Tenderer is to outline within their BCDR that also covers IT provision. |
| **Response Guidance**  | The Authority seeks to establish that the Tenderer has the necessary BCDR arrangements in place, to ensure successful deliver of the specification.The Tenderer’s response shows that it:1. Has a robust BCDR process in place to ensure continuity of services to the Authority as required by legislation.
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| ****Potential Provider Response / Additional commentary**** |
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| **Question** | **AQ11** | **Weight** | **5** | **Word Limit** | 100 |
| **Subject** | Authority responsibilities |
| **Question** | Tenderers are requested to identify any areas of responsibility that the Authority has NOT already detailed or identified within the Specification |
| **Response Guidance**  | The Authority seeks to ensure that the Tenderer is not seeking to transfer unreasonable, material, additional costs or increased risk back to the Authority.The Tenderer’s response show that it:1. The submission does not impose additional material and adverse risk, responsibility or cost on to the Authority.
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| ****Potential Provider Response / Additional commentary**** |
| Click here to enter text.  |

Appendix A – Confidential/Commercially Sensitive Information

General

All the information that we provide as part of this Contract may be regarded as the Authority’s Confidential Information.

The Contractor considers that the type of information listed in Table 1 below is Confidential Information and the type of information listed in Table 2 is Commercially Sensitive Information.

Table Types of Information that the Potential Provider considers to be Confidential

|  |  |  |  |
| --- | --- | --- | --- |
| Information considered confidential (include page/paragraph number) | Section of FOIA under which exemption is sought | Reason for exemption | Dates between which exemption is sought |
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Table 2 Types of Information that the Potential Provider considers to be Commercially Sensitive

|  |  |  |  |
| --- | --- | --- | --- |
| Information considered confidential (include page/paragraph number) | Section of FOIA under which exemption is sought | Reason for exemption | Dates between which exemption is sought |
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Appendix B - Administrative Instructions

Authorisation

## The person shown below person shall act as the Authority's Representative on all matters relating to the Contract:

|  |  |
| --- | --- |
| Name | Martin Hall - NHS Business Services Authority / Judith Hind - Department of Health Healthy Start Vitamins. |
| Contact Details | [insert details or [to be confirmed at contract award]. |

## The Authority's Representative may authorise other officers to act on their behalf.

Notices

## Any Notice the Supplier wishes to send the Authority shall be sent in writing to the Authority's Representative at the address shown in paragraph 1.1 above.

## Any notice the Authority wishes to send the Supplier shall be sent in writing to the Contractor's Representative at the address shown in paragraph 0 below.

Address for Invoices and Credit Notes

## All invoices and credit notes for the Department shall be sent to directly to Accounts Payable (AP) quoting a valid Purchase Order number (PO).

Department of Health Accounts Payable

mb-paymentqueries@dh.gsi.gov.uk

## Room 530, Richmond House, 79 Whitehall, London, SW1A 2NS

N.b. Invoices and credit notes must be sent to Accounts Payable at the above address. Invoices must not be sent to the Authority’s Representative.

Correspondence

All correspondence to the Authority except that for or relating to invoices shall be sent to the following address:

|  |  |
| --- | --- |
| Name | Martin Hall - NHS Business Services Authority / Judith Hind - Department of Health Healthy Start Vitamins. |
| Contact Details | [insert details or [to be confirmed at contract award]. |

All correspondence to the Supplier shall be sent to the following address:

|  |  |
| --- | --- |
| Name | Potential Provider to provide name |
| Contact Details | Potential Provider to provide address |

Appendix C – Parent Company Guarantee

## Potential Providers should provide a copy of this form only if a Parent Company Guarantee (PCG) is required. This should be provided on appropriate letter-headed paper and as a separate document.

## Those organisations that DO NOT require a PCG (to demonstrate financial standing) tick this box: **[ ]**

**PROVISION OF Healthy Start Vitamins - Qualified Person for Pharmacovigilance Services**

## With reference to the tender for the above services submitted by [**insert name of Contractor**] (hereinafter referred to as "the Contractor"), as a condition precedent for and in consideration of The Secretary of State for Health, (hereinafter referred to as "the Authority") entering into a contract (hereinafter referred to as "the Contract") with the Contractor for the above services, we, as the Contractor's ultimate holding company do hereby enter into the following unconditional and irrevocable undertakings with the Authority.

These undertakings being on condition that the Authority enters into the Contract with the Contractor for the above services and in consideration of the same:

The Contractor shall perform all its obligations contained in the Contract;

If the Contractor shall in any respect fail to perform the said obligations contained in the Contract or commits any breach thereof we shall ourselves perform on simple demand by the Authority, or take whatever steps may be necessary to achieve performance of the obligations under the Contract of the Contractor, and shall indemnify and keep indemnified the Authority against any loss, damages, costs and expenses howsoever arising from the said failure or breach for which the Contractor may be liable;

We shall not be discharged or released from our undertakings hereunder by any waiver or forbearance by the Authority, whether as to payment, time, performance or otherwise;

This guarantee shall be unconditional and irrevocable and shall continue in force, notwithstanding any variations or additions to or deletions from the scope of services to be performed under the Contract, until all the Contractor's obligations thereunder have been performed; and,

This document shall be construed and take effect in accordance with English Law and, furthermore, we submit to the jurisdiction of the English Courts.

**Completed by:** Click here to enter text. **Position:** Click here to enter text.

**Name:** Click here to enter text. **Date:** Click here to enter text.

**For and on behalf of** insert the name of the Potential Provider’s ultimate parent-holding company

Appendix D – Conflicts of Interest

## Potential Providers have a continuing duty to disclose actual or potential conflicts of interest in respect of itself, its named sub-contractors and / or consortia members.

Please describe any (potential) conflicts of interest that the Potential Provider has identified and how these will be managed\*:

|  |
| --- |
| ****Potential Provider Response / Additional commentary**** |
| Click here to enter text.*Guidance to Potential Providers:**You should describe in the detail the perceived conflict (how it could be perceived in the context of this procurement) and the measures it will take to mitigate the conflict through the procurement life-cycle and service delivery.* |

**If you DO NOT have any conflicts to declare, please tick this box: [ ]**

**\***Potential Providers are reminded that failure to identify material conflicts of interest may lead to rejection of its tender response.

Appendix E – Form of Tender

Declaration for Healthy Start Vitamins - Qualified Person for Pharmacovigilance Services

## Having examined the proposed Contract comprising of:

Invitation to Tender – Attachment 2 (Terms of Participation),

Invitation to Tender - Attachment 4 (Contract for the Provision of Services),

Invitation to Tender – Attachment 6 (Participation Requirements & Selection Questionnaire),

Invitation to Tender – Attachment 7 (Award Questionnaire),

Invitation to Tender - Attachment 8 (Pricing Schedule);

as enclosed in the ITT response dated [INSERT DATE]. We do hereby tender against the requirements, and terms and conditions of the proposed Contract.

We undertake to keep the tender open for acceptance by the Authority for a period of one hundred and twenty (120) days from the deadline for receipt of tenders.

We declare that this is a bona fide tender, intended to be genuinely competitive, and that we have not fixed or adjusted the amount of the tender by, or under, or in accordance with, any agreement or arrangement with any other person. We further declare that we have not done, and we undertake that we will not do, any of the following acts prior to award of this Contract:

### Collude with any third party to fix the price of any number of tenders for this Contract;

### Offer, pay, or agree to pay any sum of money or consideration directly or indirectly to any person for doing, having done, or promising to be done, any act or thing of the sort described herein and above.

We agree that the Authority may disclose the Contractor's information/documentation (submitted to the Authority during this Procurement) more widely within Government for the purpose of ensuring effective cross-Government procurement processes, including value for money and related purposes.

Unless and until the Potential Provider and the Authority have executed a formal agreement, the Authority's acceptance of this tender with all its enclosures shall not constitute a binding contract between us. We understand that you are not bound to accept the lowest price, or any, tender.

Name of person duly authorised to sign tenders:

**Date:** Click here to enter text.

**Signed:** Click here to enter text.

**In the capacity of**: Click here to enter text.

**Duly authorised to sign tenders for and on behalf of:** Click here to enter text.

By completing this Declaration and submitting your tender, you have agreed that the statements in this Form of Tender are correct.