Attachment 3 - Service Description / Specification

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1. **INTRODUCTION - Executive Summary**

The Healthy Start scheme is a statutory scheme which provides nutritional support to pregnant women, new mothers and families with children under the age of four who are on low incomes and receive ‘safety net’ benefits.

Families qualifying for the scheme receive vouchers to spend on healthy foods at participating retail outlets, and they receive a voucher which they can exchange locally for free supplies of Healthy Start vitamin products.

The Secretary of State has a statutory responsibility to make Healthy Start Vitamins available for people who are entitled to them. The Department of Health (DH) arranges for the procurement of these vitamin products, which are purchased by local authorities and distributed to Healthy Start beneficiaries. Local authorities can claim reimbursement from the DH for the cost of the vitamins.

The vitamin product for Health Start beneficiaries aged up to four - Healthy Start Children’s Vitamin drops, are presently[[1]](#footnote-2) a licensed medicine and the Marketing Authorisation (MA) is held by the Secretary of State for Health. The product is a General Sale list licensed medicine and the MA reference is PL01511 / 0003.

As the holder of the MA the Secretary of State has legal obligations to ensure compliance with licence requirements set out by the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Union (EU). Failure to fulfil these legal obligations could result in the MHRA either suspending or withdrawing the MA for this product. This in turn would mean that the Secretary of State could not meet their responsibilities to make Healthy Start Vitamins available.

The requirement for the Marketing Authorisation Holder (MAH) to have a qualified person with responsibility for pharmacovigilance services is described within the pharmacovigilance legislation (Regulation (EU) No 1235 / 2010 and Directive 2010 / 84 / EU). A legal obligation is therefore placed on the DH to meet the requirement for a qualified person (QP) who will be responsible for pharmacovigilance services. DH intends to outsource this function as described below.

1. **THE REQUIREMENT**

**Part A - On going requirements**

1. In order to meet the requirements as a MAH the DH is required to have permanently and continuously at its disposal an appropriately qualified person responsible for all aspects of pharmacovigilance in the European Economic Area. For avoidance of doubt, this requirement is for someone to be available on call 24 / 7. However, it is recognised that processes underpinning the pharmacovigilance system may be delegated by the QP to support staff.
2. The QP will be required to oversee all aspects of pharmacovigilance and will provide advice to DH on this issue, alerting DH to any potential safety issues within 24hrs during a working day and immediately to the MHRA, for which appropriate action may need to be taken.
3. The QP must provide the DH with on-going pharmacovigilance evaluation and ensure that any request from the licensing authorities, e.g. either the MHRA or the European Medicines Agency (EMA), for the provision of additional information necessary for the evaluation of the benefits and the risks afforded by a medicinal product is answered fully and promptly. The QP is obliged to answer the licensing authorities within a maximum of 15 calendar days.
4. The QP must maintain an electronic system which ensures that information about all suspected adverse reactions which are reported to the MAH is collected and collated in order to assure responsibility and liability for the licensed products on the market, and for appropriate action to be taken when necessary. This information is currently stored using an Excel spreadsheet. The QP must establish a suitable process for the on-going monitoring of all suspected adverse reactions.
5. The QP must also perform quality assurance on all aspects of the pharmacovigilance programme.
6. The QP must prepare reports referred to in the Human Medicines Regulations 2012 part 11. These include adverse drug reaction (ADR) reports, signal detection activities and any DH sponsored post-authorisation study report.
7. The QP will provide support to maintain the MA, including Periodic Safety Reports to the BSA Contract Manager and the DH Regulatory Affairs Service Provider for the Healthy Start children’s vitamin drops.

**Part B - Monthly Requirements**

1. Routine monthly requirements are as follows:-

* Weekly literature searches for signal detections.
* Maintenance of product safety databases.

**Part C - Ad-hoc Requirements**

1. There are a number of ad-hoc requirements associated with this scope of work, as follows:

* Recording and investigation of reported suspected adverse events;
  + Updating of Summary of Product Characteristics, Patient Information Leaflets and labelling including the provision of summary documents to support variation applications to the MHRA;
* Updating and maintenance of the Pharmacovigilance System Master File (PSMF);
* Input into product quality reports prepared by the product manufacturer;
  + Preparation and submission of Periodic Safety Update Reports (PSUR) to the Regulatory Authorities (although bidders should note that the next full PSUR is not required to be submitted until 2025. An extended signal detection report is prepared on a three-yearly basis in the run-up to 2025, and the next extended signal detection report is due in 2018;
* Responding to information requests from the MHRA;
* Training of staff employed by DH, Public Health England (PHE) and the Healthy Start Children’s Vitamin Drops manufacturer;
* Clinical reviews requested by DH / PHE;
* MHRA inspections;
* Input into audits of pharmacovigilance arrangements as required by legislation;
* Preparation of letters to prescribers as a result of an adverse event, potential safety issue detected by signal detection activities, or other safety related issue(s).

**Part D - Person Specification**

1. The QP will be expected to have a full knowledge of all aspects of legislation applying to ‘pharmacovigilance’ and experience of all aspects of Good Pharmacovigilance Practice.
2. The QP should either be medically qualified, or have access to a medically qualified person on a 24 / 7 basis.

**Part E - Delivery of the Requirement**

1. The costed work plan provided for the period of the contract, covering the on-going monthly and ad-hoc requirements set out above, and any ad-hoc requirements which are likely to occur during the time period covered by the work will apply.
2. Ad-hoc tasks not covered in the work plan - either those listed above, or others which may become necessary, or which may be proposed by the bidder; will be discussed in the first instance with the Contract Manager. No work should be undertaken, and no payments will be made in respect of undertaken, without the prior authorisation of the Contract Manager.
3. **AUTHORITY RESPONSIBILITIES**

During the period of the contract, the Authority Responsibilities will be:

* + The NHS Business Services Authority (NHS BSA) is responsible for the contract management and oversight of the Healthy Start Scheme, acting on DH’s behalf.

1. **CONTRACTOR RESPONSIBILITIES**

The Contractor shall:

* + Appoint a Contract Manager to oversee the work and liaise with and / or report as DH requires to the NHS BSA Contract Manager;
  + Keep the NHS BSA Contract Manager informed of Contract progress and / or issues and updates on costs on a regular on-going basis;
  + Inform the DH Contract Manager of any potential risks and potential issues as appropriate;
  + Perform quality assurance on all aspects of the project;
  + The QP will be required to attend a monthly review meeting (dates and locations to be agreed) with the Project Manager, to discuss the provision of the pharmacovigilance service as detailed above, and the quality assurance of this service. The QP will be required to produce a full report on any adverse incidents reported, and signal detection activities undertaken.

1. **TIMETABLE AND PAYMENTS**

Expenses will be paid in accordance with DH guidelines. Overnight stays will need to be authorised before the event by the Contract Manager.

Invoices for work will be submitted monthly in arrears and will be fully itemised, showing the tasks undertaken, the name / grade of the staff employed on each, and the hourly rate for each member / grade of staff. As a minimum, work should be broken down under the following headings:-

* Safety reviews / extended signal detection report;
* Compliance and Inspection;
* Weekly literature search;
* Case handling / safety database;
* Enquiry handling;
* Administration;
* Pharmacovigilance System Master File (PSMF) Production and Maintenance

1. It is the intention of the DH to re-classify this product as a food supplement thereby removing the need to hold the necessary MA licence.

   By (date) it is expect that existing stock of this product will be exhausted and MA requirements shall cease. [↑](#footnote-ref-2)