Document No. 04a

Project Title: NHS Branded Medicines Framework for North of England and Midlands and East - 1 March 2024

Offer reference number: CM/PHR/22/5678

CM/PHR/22/5678/01 - NHS Framework for NORTH OF ENGLAND Branded Medicines - Tranche B. Period of framework: 1 March 2024 to 31 August 2025 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 24 months.

CM/PHR/22/5678/02 - NHS Framework for NORTH OF ENGLAND Branded Medicines (to transition to Tranche B) Period of framework: 1 March 2024 to 31 August 2025 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 24 months.

CM/PHR/22/5678/03 - NHS Framework for MIDLANDS AND EAST of England Branded Medicines - Tranche A. Period of framework: 1 March 2024 to 31 August 2026 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 12 months.

CM/PHR/22/5678/04 - NHS Framework for MIDLANDS AND EAST of England Branded Medicines (to transition to Tranche B). Period of framework: 1 March 2024 to 31 August 2025 with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 12 months.

Quality Assurance Process

1. Risk Categorisation

1.1 The products in this tender are designated as follows, subject to paragraphs 1.2 and 1.3 below:

"E" – Elevated risk products (subject to Part A & Part B of the QA process)
"N" – Normal risk products (subject to Part A of the QA process)

Please refer to Document No. 05a(i), Document No. 05a(ii), Document No. 05a(iii) and Document No. 05a(iv), which indicate the specific designation for each product at NPCode level, subject to paragraphs 1.2 & 1.3 below. It is essential to refer to these documents as the different product risk categories have different requirements.

1.2 Any offers received for products that are over-labelled or that present in multi-lingual packs will be automatically categorised as elevated risk products regardless of whether the tender indicated the product was originally described as a 'normal' risk. As such those offered products will be assessed fully in accordance with the "E" risk products as outlined in the tender documents.

1.3 For the avoidance of doubt only those products listed within Document No. 05a(i), Document No. 05a(ii), Document No. 05a(iii) and Document No. 05a(iv), as 'elevated' products, those products that are multi-lingual or over-labelled, or those products where trusts report risk factors that are confirmed via the "elevated" product risk assessment process, will be assigned a graphic design for safety assessment category of 'Critical', 'Major', 'Other', 'No Comment'.

1.4 All offers will be subject to Part A (as described in Paragraph 2.4 of this Document No. 04a) and, offers compliant with Part A which are categorised as Elevated risk will then be subject to Part B.

2. **Quality Assurance & PharmaQC Registration Requirements**.

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

2.2 Please note Offerors **must** register the product in Pharma QC against the product pack size and NPCode description of the offered product. Where a product being offered has a different description than the tendered product (e.g specific that where the Selectt file contains a vial descriptor and the offeror wishes to offer an ampoule, this must be made clear in the "Remarks" field in Selectt and within a covering letter) the offeror **must** register their product against the ampoule description in PharmaQC.

2.3 The packaging and labelling of offered products MUST conform to the principles detailed in Document No. 7b Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines – Edition 6 and conform to the fixed gateway criteria detailed within Document No. 07b.

Any offer not supported by a supplier declaration of conformity within the ITT Supplier Questionnaire response may be deemed non-compliant and may not be taken further in the tender.

2.4 Part A Requirements

2.4.1 The requirements for Part A of the QA process, are shown in Table 1 below.

2.4.2 For the purposes of these documents approved artwork and photographs will be referred to as ‘product images’

2.4.3 Offerors must upload product images onto PharmaQC. Full details of what the approved artwork or photograph uploaded images MUST include are provided in Table 1.

2.4.4 Failure to provide image uploads as detailed in Table 1 below by the deadline given will invalidate an offer.

2.4.5 If awarded, failure to upload the PIL or SPC upon request by the deadline given in Table 1 will not satisfy the Conditions Precedent and Orders may not be placed.

Table 1

Required uploads to PharmaQC	Deadline for uploads	Images MUST clearly show	Normal Risk Products	Elevated Risk Products
Approved artwork or Photographs of Secondary Container – All faces of secondary container. For artwork this must include pack dimensions.	Tender Close	***EAN/GTIN** - number on the bar code within the image ****UK Product Licence Number/Parallel Import Product Licence number/EMEA license number (whichever apply)**	✓	✓
Approved artwork or Photographs of Primary Container - If the entire primary container label cannot be seen in one field of view (e.g. on a syringe or ampoule), multiple sequential photographs will be required. For artwork all faces of primary container must include pack dimensions	Tender Close	***EAN/GTIN** - number on the bar code within the image ****UK Product Licence Number/Parallel Import Product Licence number/EMEA license number (whichever apply)**	Not Required	✓
Approved artwork or photographs of any printed overwraps	Tender Close		Not Required	✓
Patient Information Leaflet (PiL)	If required, prior to framework commencement		Not Required (supplier has obligation to provide if awarded)	Not Required (supplier has obligation to provide if awarded)
Summary of Product Characteristics (SPC)***	If required, prior to framework commencement	****UK Product Licence Number/Parallel Import Product Licence number/EMEA license number (whichever apply)**	Not Required (supplier has obligation to provide if awarded)	Not Required (supplier has obligation to provide if awarded)

* Number on the bar code within the image should be consistent across all required images uploaded on PharmaQC for the offered product and with the number entered in the SelecTT offer file. Where a GTIN/EAN code is not yet known it should be shown as leading zeros with a trailing Z within the SelecTT offer file and consistently without a number within PharmaQC. **Any inconsistencies must be addressed in a covering letter to be submitted as part of the offer**.

** Number should be consistent across all required images uploaded on PharmaQC for the offered product and with the number entered in the SelecTT offer file.

***Where the offered product is listed in Document No 04b – Assessment Criteria, Stability Protocol and Additional Specification Requirements as having an additional specification requirement a SPC will be required by the tender closing date.

3 Part A Requirements - Methodology

3.1 The Authority, or it's nominated representatives, will follow the process outlined in steps 3.1.1 to 3.1.4 below for all products which have not had a recent Part A assessment regardless of whether they have been identified as 'normal' or 'elevated' risk (as designated in Document No. 05a(i), Document No. 05a(ii), Document No. 05a(iii) and Document No. 05a(iv), and paragraphs 1.2 and 1.3 above). For any offered product which had been assessed as a "Pass" against Part A of the QA process on, or subsequent to, 1st August 2021, confirmation that no changes have been made to the product or the associated product/information recorded in PharmaQC will be requested from the Offeror. Where an offeror confirms no changes have been made the existing "Pass" for Part A of the QA process will stand. Where an offeror confirms changes have been made the Authority will follow the process outlined in steps 3.1.1 to 3.1.4 below.

If any changes have been made to the NPC Description since the Part A has been undertaken the Authority will perform a new Part A assessment.

3.1.1 The product images and any supporting documents (where required) uploaded to PharmaQC by the tender closing date and time will be checked against the **offered** NPC Description and pack size ensuring the name, form and strength uses the approved naming convention. Any offer failing to meet the requirements at this step will be considered as 'non-compliant' and will not be taken further in the tender.

3.1.2 The uploads on PharmaQC will be checked to confirm that they meet the requirements outlined at Table 1 (above) for the respective risk category. Any offer failing to meet the requirements at this step may be considered as 'non-compliant' and will not be taken further in the tender. Offerors are advised to archive or delete images not intended to be checked as part of Part A.

3.1.3 The product images and supporting documents (where required) will be checked against the offered product details within the respective SelecTT offer. These checks include, but are not limited to, ensuring GTIN/EAN and Product License numbers and all other product details are supplied correctly and consistently on both the tender response (in the SelecTT offer file and any supporting documents) and on the uploads to PharmaQC. Any offer failing to meet the requirements at this step will be considered as 'non-compliant' and will not be taken further in the tender.

3.1.4 Offered products where specific product requirements are listed in Document No. 02 - Terms of Offer and/or Document No.4b Assessment Criteria Stability

Protocol and Additional Specification Requirements will be checked for compatibility against those specific product requirements.

4. Part B Requirements – Methodology

4.1 Once Part A has been completed, and the Authority is satisfied that the offer is compliant, the Authority, or it's nominated representatives, will follow the process outlined in steps 4.1.1 - 4.1.3 below for those offered products identified as 'elevated' risk within Document No. 05a(i), Document No. 05a(ii), Document No. 05a(iii) and Document No. 05a(iv), and paragraphs 1.2 & 1.3 above.

4.1.1 For any offer which has been assessed previously and has a "Low", or "Medium" PQA on or after 1 October 2022, confirmation that no changes have been made to the product will be requested from the offeror. Where an offeror confirms no changes have been made to the product and it still complies with all applicable requirements the existing PQA will stand. Where an offeror confirms changes have been made a Graphic Design Assessment will take place and the Authority will be able to award the products subject to a Condition Precedent, which will be signified on relevant communications as 'Subject to QC'.

If a supplier confirms that their product has not changed, but an issue is subsequently identified, e.g., by product users or QA assessors then the product may be reassessed in line with the process stated in these procurement documents. This may change the assessment given to the product.

For any offer which has been assessed previously and has a "High" PQA, the product will be re-assessed in line with the updated Graphic design for safety assessment process detailed Document No. 7b Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines – Edition 6.

4.2.3 For any offer which does not have a full PQA assessment dated on or after 1 October 2022, the Authority will be able to award to these products subject to all other award and qualifying criteria, but they will be awarded subject to a Condition Precedent, "Subject to QC" until a Graphic Design Assessment has been carried out.

4.2.4 A Graphic Design Assessment will be carried out against Document No. 7b Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines – Edition 6 and offered products must conform to the fixed gateway criteria detailed within Document No. 07b.

4.3 At the time of award any offered product where the Authority does not have a valid Graphic Design Assessment in place will be subject to Graphic Design Assessment as outlined in Document No 07b 'Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines'.