Document No. 04a

Project title: NHS National Generic Pharmaceuticals Wave 14b
Offer reference number: CM/PHG/22/5668
Period of framework agreement: The total maximum duration of the framework agreement to be no more than 24 months with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 48 months.

Potential periods of call-offs under the framework agreement:
Orals (plus non-parenteral) Products All regions 01/10/2023 to 31/05/2024 (8 months)
Hospital Only Products: DCE & DSW regions 01/10/2023 - 30/09/2025 (24 months)
Housekeeping Products (Hospital Only):
DLN & DNW regions 01/10/2023 - 31/01/2025 (16 months)
DLS & DNE regions 01/10/2023 - 31/05/2024 (8 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(iii) and Document No. 05a(v) 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(iii) and Document No. 05a(v) 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 PQA score of low, medium or high.

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 categorized as Elevated risk will then be subject to Part B (as described in Paragraph 2.5 of this Document No. 04a).

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:

Best practice guidance on the labelling and packaging of medicines (MHRA December 2020)

https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines

Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008)

NPSA-0463A-Design-for-patient-safety-V2

and for injectable medicines:
Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA 2008) ISBN: 978-1-906624-02-6

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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 Offerors must upload approved artwork and/or photographs onto PharmaQC. Full details of what the approved artwork or photograph uploaded images MUST include are provided in Appendix 1.

2.4.3 Where offerors upload approved artwork AND photographs before the tender close it is important that ALL of the images for BOTH approved artwork AND photographs identified in table 1 below and Appendix 1 are uploaded and present on Pharma QC, and they must correspond entirely with each other.

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

Table 1

Required uploads to PharmaQC	Deadline for uploads	Normal Risk Products	Elevated Risk Products
Approved artwork <u>and/or</u> Photographs of Secondary Container – see appendix 1 for detailed requirements	Tender Close	✓	✓
Approved artwork and/or Photographs of Primary Container - see appendix 1 for detailed requirements	Tender Close	✓	✓
Patient Information Leaflet (PiL)	Tender Close	✓	✓
Summary of Product Characteristics (SPC)	Tender Close	✓	✓

2.5 Part B Requirements

2.5.1 For Elevated risk products the requirements for Part B of the QA process, are shown in Table 2 below.

2.5.2 Where, for Part A, Offerors did not upload both approved artwork AND photographs, the uploads provided MUST be supplemented so that images are uploaded for BOTH approved artwork AND photographs by the deadline shown in Table 2 below.

2.5.3 Failure to upload the specified photographs and approved artwork as detailed below by the deadline given in Table 2 will not satisfy the Condition Precedent and Orders may not be placed.

Table 2

Required uploads to PharmaQC	Deadline for uploads	Elevated Risk Products
Approved artwork AND Photographs of Secondary and Primary Containers - see appendix 1 for detailed requirements	21st August 2023	✓

For the avoidance of doubt, in order for a full assessment to be made, the QA assessor needs all four of the following:

- approved artwork (galley proofs)
- photographs
- the SmPC
- the PIL

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 Documents No. 05a(i), Document No. 05a(iii) and Document No. 05a(v) 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, Wave 14a, 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.

3.1.1 The photographs and/or approved artwork and technical documents 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) and Table 1 (of appendix 1) 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. Where any single image exists of either approved artwork and/or photographs the uploads will be checked against the respective requirements. Offerors are, therefore, advised to archive or delete images not intended to be checked as part of Part A.

3.1.3 The product images and technical documents (as 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 Any offers without the required photographs AND approved artwork, that otherwise meet the eligibility and award criteria as disclosed in the Procurement Documents, will be awarded to the framework agreement subject to a "Condition Precedent" (Please refer to Document No. 3) which will be signified on relevant communications as 'Subject to QC'.

4.2 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 4.2.1 - 4.2.3 below for those offered products identified as 'elevated' risk within Document No. 05a(i), Document No. 05a(iii) and Document No. 05a(v) and paragraphs 1.2 & 1.3 above.

4.2.1 For any offer which has been assessed previously and has a "Low", "Medium" or "High" PQA on or after 1 January 2020, 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 the Authority will be able to award the products subject to a Condition Precedent, "Subject to QC" and treated as described at 4.1 above. 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 PQA given to the product.

4.2.2 For any offer where a full assessment is not possible because either photographs or approved artwork have not yet been provided, a provisional PQA assessment will be undertaken as detailed in Document No. 07b 'Quality Assurance Policy to support the National Contract Procurement of Licensed Medicines' based on the available uploaded images. Where a provisional assessment on the uploaded images identifies the characteristics for a High PQA and the QA Assessor determines that the provision of the absent factor would not change the High PQA status the PQA will be assigned the status of a 'High PQA' with supporting narrative to state that Artwork Only has been provided.

4.2.3 For any offer which does not have a full PQA assessment (including PQA assessments completed as 'Artwork Only') dated on or after 1 January 2020, 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" and treated as described at 4.1 above.

4.2.4 A PQA will be carried out against the following documents:

Best practice guidance on the labelling and packaging of medicines (MHRA December 2020)

https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines

Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008)

NPSA-0463A-Design-for-patient-safety-V2

and for injectable medicines:
Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA 2008) ISBN: 978-1-906624-02-6

NRLS-0592-guide-to-labell_medicines-(

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

APPENDIX 1

Detailed requirements for images on PharmaQC

1. Part A & Part B Requirements

1.1 All image uploads (including: photographs, approved artwork; technical documents) MUST be clear, legible, and unambiguous.

1.2 Where possible, multiple photographs for each single offered item should be saved in a single document for ease of viewing. Uploading Images of the Drug supplier database: pharmaqc user guide at https://www.gov.uk/government/publications/drug-quality-assurance-database-pharmaqc-information

<table>
<tr><th colspan="4">Image uploads - Packaging & Labelling</th></tr>
<tr><th>Description</th><th>Image type</th><th colspan="2">Images MUST clearly show</th></tr>
<tr><td rowspan="2">Image of Secondary Container - to include:
Carton, Container etc.</td><td>Photographs</td><td>All faces of secondary container</td><td rowspan="2">*EAN/GTIN - number on the bar code within the image

**UK Product Licence Number/Parallel Import Product Licence number/EMEA license number (whichever apply)</td></tr>
<tr><td>Approved Artwork</td><td>Approved artwork (or galley proofs) of all faces of secondary container - must include pack dimensions</td></tr>
<tr><td rowspan="2">Image of Primary Container - to include:
Blister pack, vial, ampoule, printed overwraps, administration devices etc. as appropriate</td><td>Photographs</td><td>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.</td><td rowspan="2">*EAN/GTIN - number on the bar code within the image

**UK Product Licence Number/Parallel Import Product Licence number/EMEA license number (whichever apply)</td></tr>
<tr><td>Approved Artwork</td><td>Approved artwork (or galley proofs) of all faces of secondary container - must include pack dimensions</td></tr>
<tr><td>Patient Information Leaflet (PiL)</td><td></td><td></td><td></td></tr>
<tr><td>Summary of Product Characteristics (SPC)</td><td></td><td></td><td></td></tr>
</table>

* 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 an MA number is not yet known it should be submitted as a date format 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**.