**Document No. 04**

**Project title: NHS National Framework for Omalizumab commencing 1st February 2026**

**Offer reference number: CM/TNS/25/5734**

**Period of framework: 1 February 2026 to 31 August 2027 with an option or options to extend (at the Authority’s discretion) for a period or periods up to a total of 24 months.**

**Published By: Medicines Procurement and Supply Chain - NHS Medicines Value & Access, NHS England**

**Quality Assurance Process**

1. **Risk Categorisation**

1.1 The products in this tender are designated as follows, subject to paragraphs 1.2 to 1.4 below:

“E” – Elevated risk products

“N” – Normal risk products

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 to 1.4 below. It is essential to refer to these documents as the different product risk categories have different documentation 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.

1.3 All offers will be subject to a Quality Assurance Assessment as described in Section 4 of this Document No. 04. The purpose of the Quality Assurance Assessment is to check conformity with the specification pre-award.

1.4 Post-award, the documentation provided by the Offerors will be reviewed and safe implementation materials will be developed.

1. **Pharma QC Registration Requirements**.

2.1 Offerors **must** fully register any offered item on Pharma QC (the Authority’s electronic application for gathering product details and organising QA assessments). All required information/images for the Quality Assurance Assessment **must** be uploaded to Pharma QC 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 against the offered product description in Pharma QC.

2.3 The packaging and labelling of offered products **must** conform to the principles detailed within this document. 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.

1. **Pharma QC Document Requirements**

3.1 The requirements for the Quality Assurance Assessment process are shown in Table 1 below.

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

3.3 Offerors **must** upload product images onto Pharma QC. Full details of what the approved artwork or photograph uploaded images **must** include are provided in Table 1.

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

**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 Pharma QC 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 Pharma QC. **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 Pharma QC for the offered product and with the number entered in the SelecTT offer file.

\*\*\* Where the offered product is listed in Document No. 04 Appendix A - Stability Protocol and Additional Specification Requirements as having an additional specification requirement an SPC will be required by the tender closing date.

**4. Quality Assurance Assessment - Methodology**

4.1 The Authority, or it’s nominated representatives, will follow the process outlined in steps 4.2 to 4.5 below for all products which have not undergone a Quality Assurance Assessment and been assessed as a “Pass” on or subsequent to, 1st December 2023 regardless of whether they have been identified as ‘normal’ or ‘elevated’ risk (as designated in Documents No. 05a(i), Document No. 05a(iii) and paragraph 1.2 above).

For any offered product which has undergone a Quality Assurance Assessment and had been assessed as a “Pass” on or subsequent to 1st December 2023, confirmation that no changes have been made to the product or the associated product/information recorded in Pharma QC will be requested from the Offeror. Where an Offeror confirms no changes have been made the existing “Pass” will stand. Where an Offeror confirms changes have been made the Authority will follow the process outlined in steps 4.2 to 4.5 below.

 If any changes have been made to the NPC Description since the Quality Assurance Assessment was undertaken the Authority will follow the process outlined in steps 4.2 to 4.5 below.

4.2 The product images and any supporting documents (where required) uploaded to Pharma QC 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.

4.3 The uploads on Pharma QC 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 **must** archive or delete images not intended to be checked as part of the Quality Assurance Assessment.

4.4 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 Pharma QC. 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.

4.5 Offered products where specific product requirements are listed in Document No. 02 - Terms of Offer and/or Document No. 04 Appendix A - Stability Protocol and Additional Specification Requirements will be checked for compatibility against those specific product requirements.

Please note that medicine packaging should comply to best practice guidance for labelling and packaging to ensure that medicines can be used safely by all patients, the public and healthcare professionals alike. Best practice principles are set out in the following documents:

* Best practice guidance on the labelling and packaging of medicines (MHRA December 2020)
* Promoting safer use of injectable medicines (NPSA Alert 20, March 2007)
* Design for patient safety: A guide to the graphic design of medication packaging (NPSA 0463A 2008)
* Design for patient safety: A guide to labelling and packaging of injectable medicines (NPSA 2008) ISBN: 978-1-906624-02-6

A Graphic Design Assessment (GDA) may be performed against offered product images to identify non-compliance with the principles set out in the above documents. However, the outcome of the GDA will **not** form part of the award criteria as detailed in Document No. 02 Terms of Offer but will be shared with Participating Authorities to aid safe implementation.

**APPENDIX A – Stability Protocol and Additional Specification Requirements**

**Stability Protocol**

Please find below a link to the Stability Protocol:



**Additional Specification Requirements (supplementary to general and regulatory)**

The NHS has additional requirements to those identified within the general specification. Those requirements are specified within this Appendix A to Document No. 04 – Quality Assurance Process.

Awards for these products will be made, where possible, to offers meeting the additional specification (subject to the offers meeting all other award criteria stated in paragraph 12.1.5 of Document No. 02 – Terms of Offer).

Offers for products that do not meet the additional specification will only be awarded to the framework agreement in the absence of any offers meeting the additional specification (subject to the offers meeting all other award criteria stated in paragraph 12.1.5 of Document No. 02 – Terms of Offer).

Offerors product information within Pharma QC will be used to determine whether offered products meet the addition requirements where possible. The Product details and pack details recorded will be used and, in the absence of the relevant fields being completed, it will be deemed that the offered product does not meet the requirement.

1. **Specific administration requirements**

N/A

1. **Packaging protection from light**

The NHS requires the following products to be contained in packaging designed to protect the product from light:

N/A

1. **Cytotoxic products in blister packs/sachets or with Child Resistant Closure (CRC)**

N/A

As stated in Document No. 04 Quality Assurance Process, Table 1, a SPC will be required as part of the tender submission on Pharma QC to ensure products are compliant with the presentation requirements stated above.

1. **Oral liquid products to have Child Resistant Closure (CRC)**

The NHS requires the following oral liquid products to have a CRC:

N/A

Where no offered product includes a CRC, the product should be such that the end-user should be able to apply one if required.

As stated in Document No. 04 Quality Assurance Process, Table 1, an SPC will be required as part of the tender submission on Pharma QC to ensure products are compliant with the presentation requirements stated above.

1. **Patient Packs**

Where offers are received for tablets or capsules or oral solutions/suspensions which do not represent the tendered pack size but represent a suitable alternative patient pack for dispensing awards will be made to the lowest-priced offered patient pack (subject to the offers meeting all other award criteria stated in criteria stated in paragraph 12.1.5 of Document No. 02 – Terms of Offer).

1. **Additional Specification Requirements**

N/A

1. **Products with labels applied over primary packaging which are used in an aseptic setting**

The NHS requires the primary container of the following products which are used in an aseptic setting to bear an original label in English (i.e. NOT over labelled).

N/A