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**Clarification Log 18th March 2025 Version 5**

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| Date Received | Clarification Question | NEYPPC Clarification Response | Response Date |
| 11/02/2025 | A supplier has highlighted an issue with the “Document 6b Product Specification Response (Form B)” and the naming protocol and that it does not allow for separate identification of documents that pertain to each products lot where provided. | We would like you to provide product specific **zip folder(s)** that are named with the product lot and product name for example:  Lot 1\_Ajmaline 50mg\_10ml\_Injection\_FormB  Where you are providing multiple alternative offers for one product lot, please follow zip folder name with “(1)”, or “(2)” for example:  Lot 1\_Ajmaline 50mg\_10ml\_Injection\_FormB (1)  Lot 1\_Ajmaline 50mg\_10ml\_Injection\_FormB (2)  Contained within each product lot zip folder should be:   * Document 6b Product Specification Response (Form B) * Supporting documents named following the naming protocol stipulated in form B | 11/02/2025 |
| 27/02/2025 | Supplier has raised a query regarding sections 24 to 27 of the Document 6b Product Specification Response (Form B) and how to document where products do not have a package leaflet or PIL or need translated documents. | Suppliers are able to clarify with a statement in the Document 6b Product Specification Response (Form B) against the identified sections to make clear as to which documents are available for each product lot. | 27/02/25 |
| 03/03/2025 | Supplier has asked if Lot 30 Patent blue 50mg/2ml solution for injection if it is a pre-filled syringe or an ampoule as the pharmaceutical form and would both forms be acceptable. | Please refer to Document 9 Commercial Schedule (Introduction) Note 8 Offer: Offerors are able to submit a maximum of **3 alternative proposals** against each product lot where applicable.  Please refer to Document 2 "Terms of Offer" point 11. NB “Alternative proposals” may be either pre-filled syringes or ampoules as long as all licensed in a trusted country as set out in Document 8 Tender Response (Component 1) specification point A3 | 04/03/2025 |
| 03/03/2025 | Supplier has asked about Latex status evidence and how this can be provided when they receive this from the supplier/manufacturer and whether the statement can be directly added to the Document 6b Product Specification Response Form (Form B) or if they are able to provide a separate document following the naming protocol. | **Within Document 6b Product Specification Response Form (Form B) states against Reference point 19 (row27)** *Do not embed documents: please provide as separate document(s) using the naming protocol [Supplier Name\_Doc6\_Form B\_19]*  **NEYPPC will accept the following methods of evidence**  Where the evidence exists as a document, please follow guidance above. However, if the evidence is given as a text statement, this can be provided as text only in cell C27 | 04/03/2025 |
| 05/03/2025 | Supplier has asked if they are able to submit their own Carbon Reduction Plan or if they have to use the template within the PPN 06/21 | The Carbon Reduction Plan (CRP) PPN 06/21 was provided as guidance. Please refer to the SSQ Section 7 Carbon Reduction questions in Atamis when completing your response. | 11/03/2025 |
| 05/03/2025 | Supplier has asked if the contract value is based on activity of members only, or members and non-members? | The contract value is based on the historic activity of consortium **members and** non-members. | 11/03/2025 |
| 05/03/2025 | Supplier has asked if we can confirm that the obligation is that hospitals must order from the supplier awarded the lot? Are there any mechanisms in place from the consortium to ensure this? | Consortium members are expected to order from the supplier awarded the lot, in line with the contract terms. While there is no formal enforcement mechanism in place and it is based on clinical preference / requirements, NEYPPC works closely with members to encourage compliance through regular engagement and performance monitoring. Members and Non-Members are asked to complete the Schedule 7 Order form prior to commencement of the contract and as part of implementation.Please refer to Document 5 NHS-framework-agreement-for-the-supply-of-goods-and-the-provision-of-services Schedule 7 Order forms Ordering Procedure, Award Criteria and Order Form. | 11/03/2025 |
| 05/03/2025 | The supplier has asked if In the case of the obligation being to order from the supplier awarded the lot, what happens if they cannot supply? | If the awarded supplier is unable to supply, NEYPPC would liaise with the supplier to understand the issue and seek a resolution. If supply cannot be restored, alternative supply arrangements would be explored to minimise disruption to patient care, in line with the contract terms. | 11/03/2025 |
| 05/03/2025 | Supplier has asked if the consortium has an expectation of the level of stockholding a supplier must have to fulfil orders, if volumes are not guaranteed? | NEYPPC does not stipulate a mandatory stockholding level. However, suppliers are expected to maintain sufficient stock levels to meet anticipated demand, based on historical usage data and any additional information provided during the contract term. Members and Non-Members are asked to complete the Schedule 7 Order form prior to commencement of the contract and as part of implementation. Please refer to Document 5 NHS-framework-agreement-for-the-supply-of-goods-and-the-provision-of-services Schedule 7 Order forms Ordering Procedure, Award Criteria and Order Form | 11/03/2025 |
| 05/03/2025 | Supplier has asked If a level of stockholding is required? Our assumption is the supplier will hold commercial risk of product – can you confirm if this is correct? | Yes, if stockholding is required to meet anticipated demand, the **commercial risk** associated with those products is expected to be borne by the supplier, unless otherwise agreed. | 11/03/2025 |
| 05/03/2025 | Supplier has said there are no questions asked regarding implementation/transition of the service from current state to new contract. What are the consortium’s expectations on service transition/implementation? | Although no formal questions were included in the tender regarding transition, NEYPPC expects suppliers to work collaboratively with members to ensure a smooth transition. This includes providing clear implementation plans, timelines, and communication strategies to minimise disruption. Members and Non-Members are asked to complete the Schedule 7 Order form prior to commencement of the contract and as part of implementation. Please refer to Document 5 NHS-framework-agreement-for-the-supply-of-goods-and-the-provision-of-services Schedule 7 Order forms Ordering Procedure, Award Criteria and Order Form | 11/03/2025 |
| 05/03/2025 | Supplier has said the commercial schedule does not appear to allow for any pricing based on, for example, minimum order quantity or volume-based discounts – whilst we recognise volumes are not guaranteed, would the consortium be willing to accept pricing on this basis, and if so, how would this be evaluated within the criteria given? | No the commercial schedule is designed to ensure consistent pricing across all members. | 11/03/2025 |
| 06/03/2025 | Supplier has asked a question regarding Lot 18 - Infloran 250 mg capsules- 1 x 20, listed in the Commercial Schedule as a 250mg strength and if this is equivalent to a 1000 Million CFU | Yes, it is equivalent, the active ingredient is: Live freeze-dried Bifidobacterium bifidum not less than 1,000 million. Live freeze-dried Lactobacillus acidophilus no less than 1,000 million. | 11/03/2025 |
| 07/03/2025 | A supplier has asked if they do not have a WDA and/or the MHRA approved “Specials” licence with the required scope to import products from trusted countries in place before the submission deadline, would they be excluded from participating in the respective sections of the tender. | Yes they would be excluded | 11/03/2025 |
| 07/03/2025 | A supplier has asked if it acceptable to embed copies of the MHRA Letters onto Document 6b Product Specification Response (Form B)? This field (C29) does **not** state "Do not embed documents: please provide as separate document" therefore the assumption is that they can embed the MHRA Letters onto individual Form B's. | Do not embed documents: please provide as separate document(s) using the naming protocol [Supplier Name\_Doc6\_Form B] against Point 21 | 11/03/2025 |
| 07/03/2025 | A supplier has asked if there is an error within the Standard Selection Questionnaire in Atamis if section 1.2 attachment of the SQ envelope which reads - “Please attach supporting documentation for Question 1.2? Would this be the area to upload supporting documentation for questions in 1.1 and not 1.2? | Yes Section 1 - Bidding Model Requirement 1.2 Attachment, should read “Please attach any supporting documentation for Question 1.1”  This has been corrected in Atamis and an amendment in the system submitted. Atamis advise that anyone that has already submitted their response **will be required to resubmit**. This will not affect any progress or response detail to date. | 11/03/2025 |
| 07/03/2025 | Supplier has asked if we can confirm if the following requirements are mandatory and if the rationale can be confirmed regarding: - MIA licence - Site Master Plan / Validation Master Plan | MIA Licence - A supplier will need to provide details and a copy of their MIA licence if held as this is a mandated point. Please refer to specification C4 Document 8 specification Tender Response Components 1 & 2. This confirms the supplier has the required scope to meet the requirements of the tender if they do not have a WDA Licence.  Site Master Plan / Validation Master Plan - Please refer to specification point C10 Document 8 specification Tender Response Components 1 & 2.  Suppliers are asked to provide a site master file and quality policy; this gives the consortium assurance the site being used for importation has the basic requirements to fulfil the service and will be judged accordingly. The key attributes are listed against this specification point. | 11/03/2025 |
| 11/03/2025 | A supplier has asked that where there is a reference to responses needing to be less that than 500 characters within Document 8 Tender Specification Response Component 1&2 and Document 6b (Form b) does this include referencing details from SOPs and exact sections within said SOPs and where do the character limitations apply | Suppliers are able to provide a reference to the SOP, page number and section and load the document as an attachment where requested to do so, using the naming protocol. A supplier is also able to load a word document with a statement of more than 500 characters where necessary.  Please refer to instructions tab Document 8a Specification Tender Response (Component 2) | 11/03/25 |
| 18/03/2025 | **A clarification question has been received after the deadline and it was felt that a response was beneficial to all suppliers.**  A supplier has asked if MHRA authorisation and license scope must be in place at the closing date of submission as they are undergoing a change control process to expand their scope. | We can confirm that the correct licence and licence scope must be in place at the time of submission commensurate with products offered.  Please refer to specification point C4 Document 8 Specification Tender Response (Component 1 & 2) | 18/03/25 |
| 18/03/2025 | **A clarification question has been received after the deadline and it was felt that a response was beneficial to all suppliers.**  A supplier has queried whether it is necessary to have / commit to £5 million worth of professional indemnity insurance for a pharmaceutical supply framework. | We can confirm this is a requirement, please refer to the Document 10 Standard Selection Questionnaire (SQ) Award Criteria Methodology Version 4 and the Standard Selection Questionnaire in Atamis. | 18/03/25 |