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| Name of Proposer: | [Insert Name of Proposer]] | | Date of final assessment report shared with UNICEF VC: | Select date |
| RFP reference: | [Insert RFP Reference Number] | | Date of preliminary assessment report shared with UNICEF VC: | Select date |
| Product offered | [ Vaccine] | | Date of debriefing of outcome of technical assessment with UNICEF VC: | Select date |
| Name of technical assessor, WHO PQT | [Insert Name Surname] | | Signature of assessor |  |
| Is the supply offer considered compliant with the technical mandatory requirements: (yes/no) | | | | Yes  No |
| **A. Review of Technical Requirements: Supply offers for products prequalified by WHO** | | | | |
| **1.1. Review of Supplier** | | | | |
| Is there any current issues or concerns related to this supplier, including upcoming reassessments based on risk assessments; accumulation of complaints or AEFIs pending? | | Yes\*  No  \*Please clarify any issues of concern. | | |
| 1.2 Review of production site, production capacity, bulk source and NRA of record | | | | |
| Is the country of origin of production identical with information provided during prequalification? | | Yes  No\*  \*Please include additional information | | |
| In case of any subcontract, is information provided identical to what was provided during prequalification? | | Yes  No\*  \*Please include additional information | | |
| Is the offered production capacity in line with the facility, including installed equipment? | | Yes  No\*  \*Please include additional information | | |
| Is additional technical information required to assess production capacity? | | Yes\*  No  \*Please include additional information | | |
| If the proposer is sourcing bulk or fill finish externally, is the source of bulk or fill finish is identical to that approved under the prequalification process. | | Yes  No\*  \*Please include additional information | | |
| Is storage capacity, if offered, in line with physical storage facility at site? | | Yes  No\*  \*Please include additional information | | |
| In case of planned or ongoing capacity expansions, please review and assess the information provided on: | | 1. Milestones and timelines related to any scale up in production capacity, including if required, any new facilities 2. Milestones and timelines for anticipated approval by the NRA 3. Timelines for WHO approval as applicable 4. Expected timeline for release and availability to UNICEF of first product from new capacity   Are there any concerns regarding the ability of the supplier to meet above milestones and timelines?  Yes \*  No  \*What would be the risk adjusted timelines for each step (6-12 months) | | |
| Is the NRA of record identical to what has been provided during prequalification? | | Yes  No\*  \*Please include additional information | | |
| 1.3 Review of cold chain requirements and shelf life | | | | |
| Is the cold chain requirement per dose consistent with the one prequalified by WHO? | | Yes  No\*  \*Please include additional information | | |
| Is the total shelf life of the vaccine offered consistent with the one prequalified by WHO? | | Yes  No\*  \*Please include additional information | | |
| Is offered shelf life at time of shipment  considered realistic? | | Yes  No\*  \*Please include additional information | | |
| For any plans to increase shelf life, are the timelines provided considered realistic? | | Yes  No\*  \*Please include additional information | | |
| 1.4 Review of programmatically preferred vaccine characteristics | | | | |
| Labelling: Primary and secondary containers labelled according to the principles set out in TRS 996, Annex 2? | | Yes  No\*  \*Please include additional information | | |
| 1.5 Review of packaging and shipping devices | | | | |
| Closures: Are the vaccines in vial presentations fitted with closures that conform with ISO standards 8362 (parts 2 through 7, as applicable) and are these consistent with the closures prequalified by WHO? | Yes  No\*  \*Please include additional information | | | |
| VVMs: Is the VVM offered in line with the VVM approved during prequalification? | Yes  No\*  \*Please include additional information | | | |
| Barcoding: | Is the barcoding on all packing levels except primary packaging confirming to GS1, with GTIN, lot number and expiry date?  At secondary packing level:  Yes  No\*  At tertiary packing level, in accordance with Annex B:  Yes  No\*  Is the barcoding also included on secondary and tertiary packing level for diluents or adjuvants?  Yes  No\*  \*Please include additional information | | | |
| Are the Packaging/Shipping arrangements in accordance with the WHO “Guidelines on the International Packaging and Shipping of Vaccines, Sixth Edition”? [[1]](#footnote-1) | Yes  No\*  \*Please include additional information | | | |
| Time temperature monitoring devices: Are the time temperature monitoring devices offered prequalified by WHO as Shipping Indicators (E006)? | Yes  No\*  \*Please include additional information | | | |
| 1.6 Any other topics | | | | |
| Are there any variations currently pending for review and approval by the WHO PQT? | Yes\*  No  \*What is the anticipated timeline for endorsement and what is the nature of the variation?  Will the variation require updates for licensure by NRAs in other countries? | | | |
| Any additional information required to assess compliance with technical mandatory requirements? | Yes\*  No  \*Please include additional information | | | |
| Any other technical information provided by proposer not included in assessment above | WHO PQT Assessor it to comment on any other elements of the technical proposal not included above: | | | |
| 1.7 Review of samples | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | **REVIEW OF SAMPLES** | Same as prequalified? | If not, acceptable justification provided for deviation? | Further clarifications required? | | Vaccine primary container including closure and label |  |  |  | | Vaccine secondary packaging and label |  |  |  | | Vaccine diluent/buffer primary container, if applicable |  |  |  | | Vaccine delivery device or any other device and material to be provided in the secondary packaging, if applicable |  |  |  | | Vaccine inserts |  |  |  | | Language versions approved as part of prequalification in line with requirements of the tender (at least English, French, and Portuguese; optional Spanish and Arabic) |  |  |  | | Inner box |  |  |  | | | | | |

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| **B. Review of Technical Requirements: Supply offers for products not (yet) prequalified by WHO** | | |
| **1.1. Review of Supplier** | | |
| Is there any current issues or concerns related to this supplier, including upcoming reassessments based on risk assessments; accumulation of complaints or AEFIs pending? | | Yes\*  No  \*Please clarify any issues of concern. |
| 1.2 Review of production site, production capacity, bulk source and NRA of record | | |
| Is the country of origin of production identical with information provided previously for assessment/prequalification? | | Yes  No\*  \*Please include additional information |
| In case of any subcontract, is information provided identical to what was provided during previous assessment/prequalification? | | Yes  No\*  \*Please include additional information |
| Is the offered production capacity in line with the facility, including installed equipment? | | Yes  No\*  \*Please include additional information |
| Is additional technical information required to assess production capacity? | | Yes\*  No  \*Please include additional information |
| If the proposer is sourcing bulk or fill finish externally, is the source of bulk or fill finish is identical to that previously assessed? | | Yes  No\*  \*Please include additional information |
| Is storage capacity, if offered, in line with physical storage facility at site? | | Yes  No\*  \*Please include additional information |
| In case of planned or ongoing capacity expansions, please review and assess the information provided on: | | a. Milestones and timelines related to any scale up in  production capacity, including if required, any new  facilities  b. Milestones and timelines for anticipated approval by the  NRA  c. Timelines for WHO approval as applicable  d. Expected timeline for release and availability to UNICEF  of first product from new capacity  Are there any concerns regarding the ability of the supplier to meet above milestones and timelines?  Yes \*  No  \*What would be the risk adjusted timelines for each step (6-12 months) |
| Is the NRA of record identical to what has been provided for prequalification/assessment? | | Yes  No\*  \*Please include additional information |
| 1.3 Review of cold chain requirements and shelf life | | |
| Is the cold chain requirement per dose consistent with what was previously assessed by WHO? | | Yes  No\*  \*Please include additional information |
| Is the total shelf life of the vaccine offered consistent with what was previously assessed by WHO? | | Yes  No\*  \*Please include additional information |
| Is offered shelf life at time of shipment  considered realistic? | | Yes  No\*  \*Please include additional information |
| For any plans to increase shelf life, are the timelines provided considered realistic? | | Yes  No\*  \*Please include additional information |
| 1.4 Review of programmatically preferred vaccine characteristics | | |
| Labelling: Primary and secondary containers labelled according to the principles set out in TRS 996, Annex 2? | | Yes  No\*  \*Please include additional information |
| 1.5 Review of packaging and shipping devices | | |
| Closures: Are the vaccines in vial presentations fitted with closures that conform with ISO standards 8362 (parts 2 through 7, as applicable) and are these consistent with the closures prequalified by WHO? | Yes  No\*  \*Please include additional information | |
| VVMs: Is the VVM offered in line with the VVM previously assessed? | Yes  No\*  \*Please include additional information | |
| Barcoding: | Is the barcoding on all packing levels except primary packaging confirming to GS1, with GTIN, lot number and expiry date?  At secondary packing level:  Yes  No\*  At tertiary packing level, in accordance with Annex B:  Yes  No\*  Is the barcoding also included on secondary and tertiary packing level for diluents or adjuvants?  Yes  No\*  \*Please include additional information | |
| Are the Packaging/Shipping arrangements in accordance with the WHO “Guidelines on the International Packaging and Shipping of Vaccines, Sixth Edition”? [[2]](#footnote-2) | Yes  No\*  \*Please include additional information | |
| Time temperature monitoring devices: Are the time temperature monitoring devices offered prequalified by WHO as Shipping Indicators (E006)? | Yes  No\*  \*Please include additional information | |
| 1.6 Any other topics | | |
| Are there any variations currently pending for review and approval by the WHO PQT? | Yes\*  No  \*What is the anticipated timeline for endorsement and what is the nature of the variation?  Will the variation require updates for licensure by NRAs in other countries? | |
| Any additional information required to assess compliance with technical mandatory requirements? | Yes\*  No  \*Please include additional information | |
| 1.7 Review and assessment of timeline for product to be available for delivery to UNICEF | | |
| Is the vaccine (previously) assessed by WHO PQT? | Yes\*  No  \*For PQ and/or EUAL?  Is the product pending assessment by WHO PQT?  Yes  No  Is the product listed under EUAL?  Yes  No  If the product has been assessed by WHO PQT, what were the main  outcomes, main recommendations/gaps and estimated timelines  for dossier completion for WHO PQ (or resubmission for EUAL)?  To what extent have the identified gaps been addressed by the supplier? | |
| Vaccine Development: Status and plans, including source of bulk antigens to be used | Any issues or clarifications required to assess the validity of the information submitted in regard to status and development plans? | |
| Clinical Trials: Trials conducted so far and planned, with timelines | Are the timelines considered realistic?  Yes  No\*  \*What would be considered a realistic timeline (6-12 months span) | |
| National Regulatory Registration: Status and plans for registration, including NRA that would be responsible for release of the finished vaccine and planned vaccine presentations | Are the timelines for registration considered realistic?  Yes No  What would be considered a realistic timeline? (6-12 months span) | |
| File submission to WHO: Status and plans. | Given the status of clinical development and national licensure, is the timeline for submission for prequalification considered realistic? Yes No\* \*What would be considered a realistic timeline? (6-12 months span) | |
| Any other technical information provided by proposer not included in assessment above | WHO PQT Assessor it to comment on any other elements of the technical proposal not included above: | |
| 1.8 Review of samples | | |
| |  |  |  |  | | --- | --- | --- | --- | | **REVIEW OF SAMPLES** | Conforms to WHO prequalification guidelines? | If not, acceptable justification provided for deviation? | Further clarifications required? | | Vaccine primary container including closure and label |  |  |  | | Vaccine secondary packaging and label |  |  |  | | Vaccine diluent/buffer primary container, if applicable |  |  |  | | Vaccine delivery device or any other device and material to be provided in the secondary packaging, if applicable |  |  |  | | Vaccine inserts |  |  |  | | Language versions approved as part of prequalification in line with requirements of the tender (at least English, French, and Portuguese; optional Spanish and Arabic) |  |  |  | | Inner box |  |  |  | | | |

1. <https://apps.who.int/iris/bitstream/handle/10665/338012/9789240015432-eng.pdf?sequence=1&isAllowed=y> [↑](#footnote-ref-1)
2. <https://apps.who.int/iris/bitstream/handle/10665/338012/9789240015432-eng.pdf?sequence=1&isAllowed=y> [↑](#footnote-ref-2)