**PART VI: ANSWER SHEETS**

# Answer Sheets / Checklist

This form serves as a checklist for preparation of your Proposal. Please complete the Answer Sheets in accordance with the instructions in the RFP document and return them as part of your Proposal submission. No alteration to format of sheets shall be permitted.

As indicated in the Part II, Section 4 of the RFP document, the Proposal must include a signed PROPOSAL FORM in original. The ANSWERING SHEETS, apart from the PORPOSAL FORM, can be submitted in MS Word format, if possible.

**Commercial Proposal**

|  |  |
| --- | --- |
| * Proposal Form |  |
| * Proposer Information Sheet |  |
| * Commercial Proposal Sheet (Quantitative & Qualitative) |  |
| * Vaccine Registration Status Sheet |  |
| * Questionnaire on disability-inclusiveness of vendors |  |
| * Supplier sustainability questionnaire |  |

**Technical Proposal**

|  |  |
| --- | --- |
| * Technical Proposal Sheet |  |
| * Packing Details Sheet |  |

**COMMERCIAL PROPOSAL**

**PROPOSAL FORM**

**Important:** The company identified as Proposer will be the party to which UNICEF will issue its LTA(s)/PO(s) in case of award resulting from this solicitation process.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Proposer: | [INSERT NAME OF PROPOSER]] | Date: | Select date |
| RFP reference: | **RFP-DAN-2023-503601** | | |

**Part 1: Declaration**

The undersigned, being a duly authorized representative of the Company, represents and declares that:

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | The Company and its Management[[1]](#footnote-1) have not been found guilty pursuant  to a final judgment or a final administrative decision of any of the following: | YES | NO |
|  | 1. Fraud; |  |  |
|  | 1. Corruption; |  |  |
|  | 1. Conduct related to a criminal organisation; |  |  |
|  | 1. Money laundering or terrorist financing; |  |  |
|  | 1. Terrorist offences or offences linked to terrorist activities; |  |  |
|  | 1. Sexual exploitation and abuse; |  |  |
|  | 1. Child labour, forced labour, human trafficking; or |  |  |
|  | 1. Irregularity (non-compliance with any legal or regulatory requirement applicable to the Company or its Management). |  |  |
| 2. | The Company and its Management have not been found guilty pursuant to a final judgment or a final administrative decision of grave professional misconduct. |  |  |
| 3. | The Company and its Management are not: bankrupt, subject to insolvency or winding-up procedures, subject to the administration of assets by a liquidator or a court, in an arrangement with creditors, subject  to a legal suspension of business activities, or in any analogous situation arising from a similar procedure provided for under applicable national law. |  |  |
| 4. | The Company and its Management have not been the subject of a final judgment or a final administrative decision finding them in breach of their obligations relating to the payment of taxes or social security contributions. |  |  |
| 5. | The Company and its Management have not been the subject of a final judgment or a final administrative decision which found they created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration, or principal place of business (creating a shell company). |  |  |
|  | The Company and its Management have not been the subject of a final judgment or a final administrative decision which found the Company was created with the intent referred to in point (5) (*being a shell company*) |  |  |

The UNICEF reserves the right to disqualify the Company suspend or terminate any contract or other arrangement between the UNICEF and the Company, with immediate effect and without liability, in the event of any misrepresentation made by the Company in this Declaration. It is the responsibility of the Company to immediately inform the UNICEF of any changes in the situations declared. This Declaration is in addition to, and does not replace or cancel, or operate as a waiver of, any terms of contractual arrangements between the UNICEF and the Company.

**Part 2: Confirmation of Proposal**

The Undersigned, having read the Instructions to Proposers of this Request for Proposal and all related documents hereby offers to supply the Goods to meet the overall objectives sought in accordance with any specifications stated, under the conditions and in quantities, at prices and within the number of days as indicated in your Proposal, and subject to all Terms and Conditions set out or specified in this **RFP-DAN-2023-503601** and accepting that any Long Term Arrangement(s) resulting from this RFP shall contain the UNICEF General Terms and Conditions and any other terms and conditions specified in this RFP.

I, the undersigned, certify that I am duly authorized by [INSERT NAME OF PROPOSER]] to sign this Proposal.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Company as per the certificate of incorporation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Postal Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Validity of Offer:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please indicate which of the following terms of payment are offered under this Proposal:

10 days 3.0% \_\_\_\_\_ 15 days 2.5% \_\_\_\_\_ 20 days 2.0% \_\_\_\_\_

30 days net \_\_\_\_\_ Other\_\_\_\_\_

Any requested EXCEPTIONS or CLARIFICATIONS to the requirements defined by UNICEF in this Request for Proposal and all related documents, including UNICEF’s General Terms and Conditions are to be described by the Proposer below. Additional pages may be attached. Request for EXCEPTIONS after an AWARD has been made may result in invalidation of the Proposal:

[*Stamp with official stamp of the proposer*]

**PROPOSER INFORMATION SHEET**

|  |  |
| --- | --- |
| Are you a UNGM registered vendor? | Yes [insert UGNM vendor number]  No\*  \*If your company has not yet registered through the UNGM, please submit an application through the UNGM website at <http://www.ungm.org/Acount/Registration>  Please note that while Basic level registration is sufficient for evaluation purposes, Proposers are highly encouraged to register at least at Level 1. |
| Are you a UNICEF vendor? | Yes  No |
| Have you provided audited financial statements to UNICEF in the past 12 months | Yes  No\*  \* If not, please proceed as per Part II, Section 1.2 of this Request for Proposal. |

**COMMERCIAL PROPOSAL SHEET**

1. **Quantitative Proposal**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Proposer: | [Insert Name of Proposer]] | Date: | Select date |
| RFP reference: | **RFP-DAN-2023-503601** | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **1. BCG Vaccine, Vial/Ampoule of 20 doses** | | | | | | |
| Quantities per year in vials and doses:  2024: 7,878,500 vials (157,570,000 doses)  2025: 7,957,000 vials (159,140,000 doses)  2026: 8,037,000 vials (160,740,000 doses)  2027: 8,117,000 vials (162,340,000 doses)  2028: 8,198,500 vials (163,970,000 doses)  The forecast represents the estimated needs for routine vaccination and supplementary immunisation activities in countries | | | | | | |
| Period | Quantity offered (doses) | Quantity offered (vials) | Price in USD\*/vial, FCA  [Insert nearest International Airport]] | Price in EUR\*/vial FCA  [Insert nearest International Airport]] | Conditions/  Discounts\*\* | Total Amount  (USD) |
| 2024 |  |  |  |  |  |  |
| 2025 |  |  |  |  |  |  |
| 2026 |  |  |  |  |  |  |
| 2027 |  |  |  |  |  |  |
| 2028 |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ALTERNATIVE PROPOSAL** | | | | | | |
| Vaccine:  Description:  Vial size:  Quantities per year in vials and doses: | | | | | | |
| Period | Quantity offered (doses) | Quantity offered (vials) | Price in USD\*/vial, FCA  [Insert nearest International Airport]] | Price in EUR\*/vial FCA  [Insert nearest International Airport]] | Conditions/  Discounts\*\* | Total Amount  (USD) |
| 2024 |  |  |  |  |  |  |
| 2025 |  |  |  |  |  |  |
| 2026 |  |  |  |  |  |  |
| 2027 |  |  |  |  |  |  |
| 2028 |  |  |  |  |  |  |

\* Offers can be in USD only (in which case only the USD column needs to be completed). If offer is provided in EURO please ensure that both USD & EURO prices are given. Please refer to Part III, Section 6.2, CURRENCY OF PROPOSALS for further information. Offers expressed only in EURO will be invalidated.

\*\* Please indicate in the column “conditions/discounts” with check mark if there are any conditions/discounts associated with the price offered in your Proposal. Please outline the details of the conditions/discounts below (Please refer to Part III, Section 6.8).

|  |
| --- |
|  |

1. **Qualitative Proposal**

|  |  |
| --- | --- |
| **Experience and past performance. Account management.** | |
| 1 | Demonstrate proven experience and qualification in development, supply and delivery of vaccines and/or biologicals, including the offered product(s). Advice number of years of experience in production and delivery of the offered product. *(Part III, Section 1)*  Proposers response: |
| 2 | For Proposers with less than 3 years of experience as a vaccine supplier to UNICEF, please provide a full customer reference list, delivery report and delivery performance report for the minimum period of the past 3 years. Advise of the reasons for delays in deliveries and frequency, as well as measures taken to resolve the delays. Please also advise the total annual quantities supplied to other customers. *(Part III, Section 1)*  Proposers should be prepared to substantiate the claimed experience by presenting copies of relevant documents and references if so requested by UNICEF.  Proposers response: |
| 3 | Provide organizational charts and names of the responsible persons within each following department: Production, Quality Assurance, Governmental Affairs, Shipping/Logistics, Sales and Marketing, Environmental Social and Governance (ESG) specifying the name(s) of the person(s) who will be the primary contact for UNICEF. *(Part III, Section 3)*  Proposers response: |
| **Pricing** | |
| 4 | Given that UNICEF has requested prices that are affordable to the poorest country governments and donors please indicate factors influencing your price setting. Please also provide explanation of any price increase over previous years’ pricing (if applicable). *(Part III, Section 6).*  Proposers response: |
| **Volumes offered, timelines** | |
| 5 | Proposed Quantity: Explain the key determinants for the proposed quantity to be available during the proposed timeframe, as well as any key risks.  Proposers response: |
| 6 | Delivery preparation lead time (administration of UNICEF’s Purchase Order, packing, markings etc.) for any order within above mentioned schedule, in number of days (*Part III, Section 7*):  Proposers response: |
| 7 | Please include in your Proposal timelines for bulk production (from start of the production process until bulk is ready for formulation and filling) and timelines for formulation, filling, labelling, and having the product released both internally and by the relevant NRA. If the vaccine bulk is not produced by the Proposer, please advise of source of bulk, and evidence of contractual access to bulk  Bulk production:  Formulation:  Filling:  Labelling and Internal release process:  NRA release:] |
| 8 | Please provide information on your medium and long-term plans for production of the vaccine(s) being offered, or of vaccines that may be offered in the future, including overview of business factors affecting the decision to produce the vaccine at the quantities offered to UNICEF. *(Part III, Section 2)*  Proposers response: |
| 9 | Please advise whether the production of any of the vaccines offered affects the production, or potential production, of another vaccine being offered or supplied by your company. If yes, please advise which vaccines. In addition, please indicate whether facilities for bulk production and fill and finish are dedicated, multipurpose and/or shared facilities.  Proposers response: |
| 10 | Please advise if the company will be able to supply quantities above the forecast and indicate the lead times for each product offered as part of your Proposal, for quantities above forecast. |
| **Other** | |
| 11 | Storage of vaccines shall be under controlled environmental conditions to facilitate the conservation of the vaccines. Vaccines will be kept at the manufacturers’ premises until these are either supplied through UNICEF Purchase Order(s) or reach expiry date. Please confirm that your company will bear the responsibility and cost of destruction should the vaccines, by any event, reach expiry date when stored at your warehouse.  Proposers response: |
| 12 | Please confirm willingness to provide additional documentation when requested by countries.  Bidders response: |
| 13 | Please provide your company’s ESG policy (or equivalent) and confirm contact persons and their e-mail addresses with whom UNICEF can engage on questions connected to progress on environmental and social sustainability implementation operations. |

**MONTHLY OFFERED QUANTITIES (DOSES)**

**Vaccine offered: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |
| --- | --- |
| **Quantities offered, in doses** | |
| January 2024 |  |
| February 2024 |  |
| March 2024 |  |
| April 2024 |  |
| May 2024 |  |
| June 2024 |  |
| July 2024 |  |
| August 2024 |  |
| September 2024 |  |
| October 2024 |  |
| November 2024 |  |
| December 2024 |  |
| **TOTAL 2024** |  |
| Q1 2025 |  |
| Q2 2025 |  |
| Q3 2025 |  |
| Q4 2025 |  |
| **Total 2025** |  |
| Q1 2026 |  |
| Q2 2026 |  |
| Q3 2026 |  |
| Q4 2026 |  |
| **Total 2026** |  |
| **Total 2027** |  |
| **Total 2028** |  |

**VACCINE REGISTRATION STATUS SHEET**

Please list the completed registrations for each vaccine and each presentation included in the Proposal. Rows may be added to the table as necessary. *(Part III, Section 1)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product** | **Presentation** | **Country** | **NRA name** | **Date of registration** | **Date of expiry** | **Registration reference** | **Intention to renew** | **For use in private market or national program** |
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Please provide any additional information on planned and pending registrations. *(Part III, Section 2):*

**Questionnaire on disability-inclusiveness of vendors**

UNICEF is committed to implement the [United Nations Disability Inclusion Strategy](https://www.un.org/en/content/disabilitystrategy/) (UNDIS). As part of the implementation of the UNDIS, UNICEF promotes purchasing from disability-inclusive vendors and encourages its vendors to be inclusive of persons with disabilities.

A disability-inclusive vendor is a vendor which makes a dedicated, consistent, and measurable effort to implement disability-inclusive practices. Vendors can show that they are disability-inclusive through a variety of means such as, for instance, having an organizational policy on disability inclusion, recruiting and hiring people with disabilities, offering reasonable accommodation to candidates and personnel with disabilities, providing accessible premises, ensuring that their supply chains are disability-inclusive, or manufacturing accessible products following Universal Design principles.

UNICEF is interested in the efforts made by its vendors towards including persons with disabilities and would like to collect information about such initiatives. Vendors who wish to do business with UNICEF must complete this questionnaire on disability-inclusiveness. It is important to note that the answers provided will not preclude a vendor from participating in UNICEF’s business, i.e. the **provided answers will not be factored in the final evaluation for making the award decision.**

|  |  |
| --- | --- |
| **Questionnaire** | |
| 1 | Do you have a general disability-inclusion policy? If yes, please provide details.  Proposers response: |
| 2 | Do you have a policy that promotes the employment of persons with disabilities (this does not need to be specific and could be part of the general human resources policy)? If yes, please provide details.  Proposers response: |
| 3 | Do you employ persons with disabilities? If yes, please provide details.  Proposers response: |
| 4 | Do you have a policy that foresees the provision of reasonable adjustments to persons with disabilities (e.g. applicants, employees, suppliers, visitors) who so require? If yes, please provide details such as, for instance, a registry of requests for adjustments made and their status.  Proposers response: |
| 5 | Do you require your suppliers to be disability-inclusive? If yes, please provide details such as a respective policy or written agreements you may have.  Proposers response: |
| 6 | Do you engage or consult persons with disabilities in the development of your products or services? If yes, how?  Proposers response: |

## **SUPPLIER SUSTAINABILITY QUESTIONNAIRE**

**Introduction**

UNICEF is committed to making a measurable contribution to the Sustainable Development Goals through sustainable procurement by working closely with the private sector, partners, governments, civil society organisations and other UN agencies. To this end, UNICEF published its [policy on sustainable procurement](https://www.unicef.org/supply/files/UNICEF_Procedure_on_Sustainable_Procurement.pdf). UNICEF seeks to incrementally and progressively adopt a sustainable procurement approach for procurement activities to address broader environmental and social issues wherever and whenever feasible with consultation with suppliers and other stakeholders mentioned above. UNICEF would like to invite suppliers to share sustainability efforts in the supply chains. Although UNICEF will not use the information shared by suppliers for contract making award decision, this will be an opportunity to gain intelligence on sustainable procurement practice in the market. We would appreciate if you could answer all question fully.

1. **Environmental policy**
   1. a. Do you have a formal environmental policy in place? (Y/N)

b. If yes, please share a copy of the policy**.**

1. **Environmental Management System**
   1. a. Do you have an Environmental Management System in place certified by an external authorised certification body (e.g. ISO14001 or Eco-Management and Audit Scheme (EMAS))?
2. If yes, please share a copy of the certificate(s).

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **CO2 emissions**
   1. a. Have you measured your CO2 emissions? (Y/N)

b. If measured, please report your total annual CO2 emissions in the most recent year measured.

c. Have you set publicly available CO2 emission reduction targets? (Y/N)

d. If yes, what are those targets? (Enter total metric tons and target date)

1. **Waste management**

Please, refer to[WHO guideline for safe management of wastes from health-care activities](https://www.who.int/publications/i/item/9789241548564), 2nd edition, 2014

* 1. a. Do you have an operational procedure for managing or treating your solid and water waste, including hazardous and non-hazardous waste? (Y/N/NA)

b. If yes, please share a copy of the procedure.

* 1. Please share a copy of certificates issued by local authorities or any subcontracted company handling your waste.

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­­

* 1. a. Have you measured *solid waste* generated from the facilities that produce your products for UNICEF? (Y/N)

b. If measured, please report total amount of *solid waste* generated from the facilities that produce your products for UNICEF for the most recent year measured (Enter total metric tons).

c. Have you set publicly available *solid waste* reduction targets? (Y/N)

d. If yes, what are those targets? (Enter total metric tons and target date)

* 1. a. Have you measured *water waste* generated from the facilities that produce your products for UNICEF? (Y/N)

b. If measured, please report total amount of *water waste* generated from the facilities that produce your products for UNICEF for the most recent year measured (Enter total m3).

c. Have you set publicly available *water waste* reduction targets? (Y/N)

d. If yes, what are those targets? (Enter total metric tons and target date)

1. **Resource consumption**
   1. a. Have you measured total energy use from the facilities that produce your product(s) for UNICEF? (Y/N)

b. If measured, please report total amount of energy use from the facilities that produce product(s) for UNICEF for the most recent year measured (Enter total kWh).

c. Have you set publicly available energy use reduction targets? (Y/N)

d. If yes, what are those targets? (Enter total metric tons and target date)

* 1. a. Have you measured total water use from the facilities that produce our product(s) for UNICEF? (Y/N)

b. If measured, please report total water use from the facilities that produce your product(s) for UNICEF for the most recent year measured. (Enter total m3)

c. Have you set publicly available water use reduction targets? If yes, what are those targets? (Enter total m3 and target date)

1. **Policy to incorporate social accountability**
   1. a. Do you have a formal policy that covers the following areas described in the UN Supplier Code of Conduct? (Note: it could be one overarching policy/code of conduct or multiple policies)
2. Freedom of Association and Collective Bargaining (Y/N)
3. Forced or Compulsory Labour (Y/N)
4. Protection and Safeguarding of Children (including Child Labour) (Y/N)
5. Discrimination (Y/N)
6. Wages, Working Hours and Other Conditions of Work (Y/N)
7. Health and Safety of the workplace (Y/N)
8. Human Rights (Y/N)
9. Harassment, Harsh or Inhumane Treatment (including Sexual Exploitation and Abuse) (Y/N)
10. Non-engagement of sales or manufacturing of Mines (Y/N)

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## **TECHNICAL PROPOSAL SHEET**

Proposers are requested to submit one technical proposal form for each vaccine product/presentation offered:

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Proposer: | [Insert Name of Proposer]] | Date: | Select date |
| RFP reference: | **RFP-DAN-2023-503601** | | |
| Vaccine description |  | | |
| Qty offered, in doses and vials: | 2024: doses/vials:  2025: doses/vials:  2026: doses/vials:  2027: doses/vials:  2028: doses/vials: | | |
| WHO pre-qualified product | Yes  No\*  \*If no, please include information requested as per Section IV, 15: Proposals of Vaccines not yet WHO Pre-Qualified. | | |
| Language on label/package insert | Label:  Package insert: | | |
| Samples | Yes If samples provided are different from those submitted to WHO for pre-qualification, the differences should be explained:  No  Please provide justification as per Section 3.5 of Part II: | | |
| Vaccine Vials Monitor (VVM) | Yes  No  If yes, which type:  If no, please indicate feasibility to include VVM in the future, including timeline: | | |
| Bar codes | At secondary packing level, in accordance with Annex C:  Yes  No  At tertiary packing level, in accordance with Annex C:  Yes  No  Please advice type of barcode which is included (i.e. GSCC barcode, 2D Data Matrix barcode) and at which level of packing:  Please provide information on bar code inclusion on secondary and tertiary packing level for diluents or adjuvants:  For UNICEF’s information only, but not part of evaluation:  Serialisation: Please advise if serialisation is already implemented and if not, whether you are working towards including serialisation, including the timeline for implementation.  *Note:* Serialisation is not required however, specifications for such are also included as part of Annex C. | | |
| Continuous quality assurance | In the past, how has your company been able to maintain the quality level for the supplied products? If your company has faced quality problems, please provide frequency and explanations as well as measures taken for improvement. | | |
| Total annual production capacity | Bulk:  Final filled product for the offered vaccine:  Source of bulk:  Source of fill and finish:  If you are not bulk producer, or you do not perform the fill and finish for the product offered, please include evidence of contractual access to bulk/fill and finish capacity. | | |
| Batch size | Please provide minimum and maximum batch size for bulk production:  Please provide minimum and maximum batch size (throughput) for fill and finish: | | |
| Storage capacity | Please indicate cold storage capacity for bulk and finished product, indicating the maximum storage capacity in number of doses at any time.  Bulk:  Finished product: | | |
| Capacity Expansion | In case of plans to scale-up production, please provide information 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   Proposers response: | | |
| Shelf life | Remaining minimum shelf life at the time of shipment:  Total shelf life of the vaccine offered:  Please provide information on any plans to increase the current total shelf life of the vaccine including the timelines related to anticipated approval by the NRA and WHO, as applicable. | | |
| Vaccination schedule: | Proposers response: | | |
| Country of Origin: | Proposers response: | | |
| National Regulatory Authority (NRA) of record: | Proposers response: | | |
| Variations/changes to licensure and WHO prequalification dossier | Are there any variations currently pending for review and approval by:  NRA of record  Yes  No  WHO PQT  Yes  No  If you answered “yes” to any of the above, please provide information on the nature of the variation, what is the anticipated timeline for endorsement and whether the variation will require updates for licensure by NRAs in other countries.  Proposers response: | | |

## **PACKING DETAILS SHEET**

Proposers are requested to provide UNICEF with packing details for each vaccine product offered using this form:

|  |  |
| --- | --- |
| Vaccine description |  |
| Type of coolant | Ice packs  Dry Ice\*  \*If the vaccine is packed using dry ice, please advise of any plans to change to packing with ice packs. Also, please advise of any effect this would have on quantity, weight and dimension. |
| Type of time temperature monitoring device |  |
| **PACKING** | |
| |  |  |  | | --- | --- | --- | | **Standard EXPORT Packing Dimensions**  **and Weight** | Vaccine | Diluent | | Total no. of Doses per EXPORT Packing |  |  | | Total no. of Vials per EXPORT Packing |  |  | | Dimensions:  Length  Width  Height |  |  | | Gross Weight |  |  | | Net Weight |  |  | | Number of inner cartons per EXPORT Packing |  |  | | |
| |  |  |  | | --- | --- | --- | | **Standard INNER CARTON Packing Dimensions and Weight** | Vaccine | Diluent | | Total no. of Doses per INNER carton |  |  | | Total no. of Vials per INNER carton |  |  | | Dimensions:  Length  Width  Height |  |  | | Gross Weight |  |  | | Net Weight |  |  | | |

1. “Management” means any person having powers of representation, decision-making or control over the Organization. This may include, for example, executive management and all other persons holding downstream managerial authority, anyone on the board of directors, and controlling shareholders [↑](#footnote-ref-1)