REQUEST FOR PROPOSAL

UNITED NATIONS CHILDREN'S FUND (UNICEF)

wishes to receive proposals for

JAPANESE ENCEPHALITIS ('JE') VACCINES

FOR DELIVERY FOR THE PERIOD OF 2015
(with possibility of extension for additional 6 months)

RFP-DAN-2014-501825

07th May 2014

SEALED PROPOSALS must be received at the following address up to 16h00 hours (Copenhagen time) on 23rd May 2014.

UNITED NATIONS CHILDREN'S FUND (UNICEF)
Attention: BID SECTION RFP-DAN-2014-501825
Oceanvej 10-12
2150 Nordhavn, Copenhagen
Denmark
Tel +45 4533 5500

PROPOSALS RECEIVED IN ANY OTHER MANNER WILL BE INVALIDATED

Prepared by: Sonia Freitas Heurlin, Contracts Specialist

Reviewed by: Jay Barral-Guerin, Senior Contracts Manager

Approved by:

Ms. Meredith Shirey
Chief, Vaccine Centre

Ms. Safia Robinson
Chief, Contracting Centre

Ms. Shanelle Hall
Director
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1. PURPOSE

The purpose of this Request for Proposal (RFP) is to establish long-term arrangement(s) (LTAs) for the supply of Japanese Encephalitis (JE) vaccine for GAVI-supported introductions and catch-up campaigns during 2015 with possibility of an extension of an additional 6 month period to cover introductions in 2016 and possible demand for routine programmes from countries having introduced the vaccine.

These arrangements will provide the basis upon which purchase orders will be made for JE vaccine deliveries throughout the period.

Moreover, while the proposed validity timeline for this tender is limited to 2015, UNICEF is herewith inviting current and future manufacturers of JE vaccine to submit, in the frame of this tender, proposals explaining the current status of their production of JE vaccine, projections and expected production beyond the period of the current tender and future plans to submit product application for WHO pre-qualification. All these data will be gathered and analysed with a view on a future tender to take place in the first quarter of 2016.
2. BACKGROUND

2.1 THE JAPANESE ENCEPHALITIS PROGRAMME

Japanese Encephalitis (JE) is the leading cause of viral encephalitis in many countries in Asia and the Western Pacific, causing almost 70,000 cases annually\(^1\). The disease claims the lives of 20-30 percent of infected infants and children\(^2\). The infection is mosquito-borne and caused by the JE virus and predominantly found in rural and periurban locations\(^3\).

In all regions where the disease is considered to be a public health problem, the World Health Organization (WHO) recommends JE immunization as preventive measure since there is no effective treatment once the infection is contracted\(^4\). To control outbreaks in JE endemic settings in Asia, WHO recommends the implementation of a one-time catch-up campaign in high-risk populations, followed by incorporation of JE vaccines into the routine childhood immunization programme (see footnote 2).

In 2011, the GAVI Alliance (GAVI) Board recommended opening a window for country applications for GAVI support, subject to the pre-qualification of a suitable JE vaccine. In 2013 WHO pre-qualified a JE vaccine for paediatric use. Following this pre-qualification, GAVI is now inviting eligible countries to apply for support to introduce the vaccine (closing date for the first round of applications for JE vaccine was 01\(^{st}\) May 2014). The first GAVI-supported JE vaccine introduction campaigns are expected to start in 2015.

The targeted population will be children aged from 9 months and up to 15 years of age.

GAVI will provide support to JE catch-up campaigns:

- For a single dose course; and
- With the condition that countries will self-finance JE vaccine introduction in their routine immunization programs after the conclusion of the catch-up campaign. To this effect, and as part of their application to GAVI, countries will be required to demonstrate how JE vaccine will be introduced into the routine programmes after the completion of the initial introduction.

Some GAVI eligible countries have already commenced JE vaccination programs either through routine or campaigns. These countries would also be eligible to apply for support from GAVI in order to increase their immunization rates.

As indicated in the Strategic Demand Forecast (SDF) prepared by the GAVI Secretariat, GAVI-supported campaigns may require +75 million doses by 2020\(^5\), in addition, about 20 million doses are expected for routine immunization.

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However, it is important to highlight that there are challenges to quantify the actual demand, as this is a new introduction programme and applications to GAVI are still to be submitted for introduction in 2015 and onwards. To support the programme, UNICEF is launching this first tender exercise to procure JE vaccine, lyophilised, 5 doses per vial, as per GAVI Application Guideline. But UNICEF Supply Division welcomes proposals for other presentations. UNICEF will procure on behalf of one or several GAVI-supported countries, this constituting an important milestone in GAVI’s vaccine goal of accelerating the uptake and use of (underused and) new vaccines by strengthening country decision-making and introduction.

## 2.2 PROCUREMENT OBJECTIVES

The overall goal of this tender and the subsequent procurement is Vaccine Security – the sustained uninterrupted supply of affordable vaccines of assured quality to meet the first introductions into GAVI-supported countries, with the following specific objectives:

- To secure supply of JE vaccine to meet the expected demand of GAVI countries for catch up campaigns as well as introduction into routine immunization phase during 2015-2016;
- To access an affordable vaccine for GAVI and countries; and,
- To support the development of a healthy market.

## 2.3 PROGRAMMATIC DEMAND FORECAST

As mentioned previously, the actual demand is difficult to quantify due to uncertainty of the number of countries that will apply in 2014 for introductions of JE vaccine in 2015.

The below table shows the approximate forecasted requirements for JE, for the period of this tender. It is understood that once the number of countries and their specific demands are known, UNICEF, in the frame of this tender, will liaise with manufacturers having made an offer to further refine the actual quantities needed and final awards will be made on the most accurate forecast figures available at the time.

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>2016</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual Estimated Demand</td>
<td>2,000,000</td>
<td>5,250,000</td>
<td>7,250,000</td>
</tr>
</tbody>
</table>

Note: The numbers above are estimates
Source: GAVI Alliance, SDF.9 (2014)
Key demand drivers and uncertainties are:

- Window for application for GAVI support opened in February and will close on May 1st 2014, with applications expected for first introduction in Q1 2015, while in order to meet expected delivery times the present tender is launched before the actual demand has been substantiated,
- Timing of GAVI approvals,
- Country readiness (vaccine registration/licensure in countries to introduce it; training of health workers in the specifics of the administration of this vaccine, cold chain requirements, etc),
- Number of countries that will introduce (catch up campaign) and later will include JE as part of their regular immunisation programmes,
- Global availability of the vaccine.

2.4 TENDER DURATION

The validity of the tender will be for one year (as from the conclusion of the tender and issuance of award letters) with possibility of an extension of additional 6 months.

This is considered to be the most appropriate time frame to secure vaccine availability for the expected initial introductions while providing more visibility and accuracy for the global demand and demand through UNICEF.

2.5 MINIMUM QUANTITY GUARANTEES AND FIRM CONTRACTING

UNICEF, together with partners, is trying to mitigate manufacturer related risks and uncertainty by providing to manufacturers the opportunity to present comprehensive proposals through the RFP process.

In this sense UNICEF will consider innovative approaches to contracting, such as (e.g.) volume-based firm commitments, as part of the manufacturers’ proposals provided they help achieve the objectives of the tender.

Subject to funding availability, such a commitment would be conditional upon a reciprocal commitment from an awarded supplier to a defined quantity over a defined time period. Alternative contracting terms may be presented by all potential suppliers by as a part of the proposal submitted in response to this RFP.

2.6 PROCUREMENT REFERENCE GROUP

A Procurement Reference Group (PRG), comprised of independent and partner experts may be established. The role of a PRG is to provide input and advice to UNICEF and GAVI for countries receiving funding for JE vaccine from GAVI. During this process, UNICEF shares summary information related to the offers and recommended awards with the PRG under strict confidentiality. Independently of the establishment or not of a PRG, confidential consultation among partners, in respect to the offers and recommended award, will take place.
3. INSTRUCTIONS TO PROPOSERS

3.1 PROCUREMENT ARRANGEMENTS

3.1.1 UNICEF wishes to enter into non-exclusive Long Term Arrangements (LTAs) for the procurement of JE vaccine. This product would be required from time to time during the term of the LTA. It will be a provision of such LTA, that, unless specifically stated otherwise in the LTA, UNICEF will not be committed to purchase any minimum quantity of these items. UNICEF shall not be liable for any cost in the event that no purchases are made under any resulting LTAs.

3.1.2 Purchases will be made against Purchase Orders to be issued by UNICEF in accordance with the terms and conditions of any resulting LTA(s). Actual quantities to be purchased will vary from Purchase Order to Purchase Order.

3.1.3 The quantities outlined in this Request for Proposal (RFP), are estimated forecasts for the total requirements for the duration of the LTA(s). The estimates are provided in good faith and shall not in any way be deemed to be commitments on the part of UNICEF regarding any quantity for future purchase.

3.1.4 Any resulting LTAs intend to cover deliveries during the period 2015 with possibility of extension of additional 6 months period.

3.2 MANDATORY REQUIREMENTS

Mandatory requirements identify the minimum requirements for the proposals to be considered. Mandatory requirements will be indicated throughout this RFP by the words "mandatory", "shall", "must", or "will" in regard to obligations on the part of the Proposer. Proposals that do not meet the mandatory requirements will not be eligible for award.

Refer to Section 4.8.4 for instruction on how proposals that do not meet the technical mandatory requirements will be managed.

3.3 RESPONSE FORMAT

The Proposer is invited to develop a proposal that provides a comprehensive explanation of the offer being made. The proposal must include a signed PROPOSAL FORM in original. ANSWER SHEETS have been provided to assist in the organisation of the proposal.

Each proposal should:
- Contain information on mandatory requirements for offered products (MANDATORY REQUIREMENTS SHEET)
- Contain qualitative information on account management, proven experience and past performance (QUALITATIVE PROPOSAL SHEET).
- Define the proposed vaccine(s) (QUANTITATIVE PROPOSAL SHEET(S)). Sample table attached (page 26).
- Contain packing details for each one of the vaccine products offered (PACKING DETAILS SHEET(S)).
- Provide explanations to any request for exceptions or clarification on the COMMERCIAL TERMS SHEET.

The Proposer must provide sufficient information in the proposal to address each area of evaluation to ensure a fair assessment of the company can be conducted.
3.4 MARKING AND RETURNING PROPOSALS

3.4.1 Sealed proposals must be securely closed in a suitable envelope, clearly MARKED on the outside with the PROPOSAL NUMBER, and dispatched to arrive at the UNICEF office indicated NO LATER THAN the CLOSING TIME AND DATE. PROPOSALS received in any other manner will be INVALIDATED.

3.4.2 Proposals received without the PROPOSAL NUMBER will be invalidated.

3.4.3 Two (2) copies of the sealed proposal are to be submitted (only one of which is required to be original).

3.5 TIME FOR RECEIVING PROPOSALS

3.5.1 Sealed proposals received prior to the stated closing time and date will be kept unopened. The Officer of the Bid Section will open the proposal when the specified time has arrived, and no proposal received thereafter will be considered.

3.5.2 UNICEF will accept no responsibility for the premature opening of a proposal which is not properly addressed or identified.

3.6 PUBLIC OPENING OF PROPOSAL

Due to the nature of the RFP, there will be no public opening of proposals.

3.7 REQUESTING INFORMATION FROM UNICEF DURING THE TENDER PROCESS

Any request for information regarding the specifications should be forwarded to the Contracts Specialist, Ms. Sonia Freitas Heurlin (email: sfreitas@unicef.org), and NOT to the Bid Section (see front page).

Inquiries received less than seven (7) calendar days prior to the proposal closing date cannot be guaranteed any response. Only written inquiries will be entertained. A response to written queries will be provided to all Proposers in writing or through electronic communication and posting. Information provided verbally will not be considered a fundamental change and will not alter this RFP.

3.8 ERROR IN PROPOSAL

Proposers are expected to examine all Schedules and all Instructions pertaining to the work or proposal. Failure to do so will be at Proposers’ own risk. In case of errors in the extension price, unit price shall govern.

3.9 CORRECTIONS

Erasures or other corrections in the proposal must be explained and the signature of the Proposer shown alongside.
3.10 MODIFICATION AND WITHDRAWAL

3.10.1 All changes to a proposal must be received prior to the closing time and date. It must be clearly indicated that it is a modification and supersedes the earlier proposal, or state the changes from the original proposal.

3.10.2 Proposals may be withdrawn on written or faxed request received from Proposers prior to the opening time and date. Negligence on the part of the Proposer confers no right for the withdrawal of the proposal after it has been opened.

3.10.3 Modifications to and possible withdrawals of proposals must only be sent to the Bid Sections Fax + 45 35 25 02 80 (secure fax).

3.11 VALIDITY OF PROPOSALS

Proposals should be valid for a period through 31st July 2016. The Proposers are requested to indicate the validity period of their proposal. UNICEF may request the validity period to be extended.

3.12 CURRENCY OF PROPOSALS

Failure to quote in the currency stated in the RFP document, Terms and Conditions referred to in Section 4.7.7, will invalidate the proposal.

3.13 INCOTERMS

Failure to quote in accordance with the requested INCOTERMS may result in invalidation of your proposal.

3.14 SUPPLIER REGISTRATION AND EVALUATION

3.14.1 UNICEF is part of the United Nations Global Marketplace (UNGM) (previously the UN Common Supplier Database.) Accordingly, all Proposers must apply to become a UNICEF supplier and this must be done via the UNGM website at http://www.ungm.org. Following this application, the UNGM informs the UNICEF Quality Assurance Supplier Evaluation Unit (SEU) automatically, and a determination will be made as to whether the application will be accepted. The determination is based on relevance of the products to UNICEF, together with a financial assessment.

3.14.2 Simultaneously with application to UNGM, and unless this information has already been provided to UNICEF within the previous 12 months, Proposers shall submit their most recent Audited Financial Statement and Quality System Certificate to the UNICEF Quality Assurance Supplier Evaluation Unit, UNICEF Supply Division, Oceanvej 10-12, 2150 Nordhavn, Copenhagen, Denmark. This information will be used by UNICEF for evaluation and approval purposes before making an award. It is in the interest of the Proposers to provide information which is as complete as possible, as awards will only be made to suppliers who meet UNICEF’s supplier selection criteria.

3.15 COUNTRY OF ORIGIN

Proposers shall advise as to the country of origin of products offered. Proposers may furthermore be required to submit a Certificate of Origin of Goods issued by the Chamber of Commerce or other equivalent authority.
3.16 RIGHTS OF UNICEF

3.16.1 UNICEF reserves the right to INVALIDATE fully or partially any proposal received for the reasons mentioned above.

3.16.2 UNICEF reserves the right to INVALIDATE any proposal received from a Proposer who, in the opinion of UNICEF, is not in a position to perform the contract.

3.16.3 UNICEF reserves the right to request additional or supplementary data from the Proposer.

3.16.4 UNICEF reserves the right to re-tender should the result of the tender be deemed nonresponsive by UNICEF.

3.17 CATALOGUES

Proposers, who have not already done so, are kindly requested to send a copy of their current catalogue or list of product offerings.

3.18 ANSWER SHEETS

Only the forms and sheets provided in Section 5 should be used to present the various aspects of the proposal. Supplemental information can be provided on each of the ANSWER SHEETS:

- PROPOSAL FORM
- TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET
- QUALITATIVE PROPOSAL SHEET
- QUANTITATIVE PROPOSAL SHEET(S)
- PACKING DETAILS SHEET(S)
- COMMERCIAL TERMS SHEET

3.19 AWARD NOTIFICATION / PUBLIC POSTING

All Proposers will receive a written notification regarding the results of their proposal.

UNICEF will make each award public by publishing the following information on the UNICEF website: The supplier name, vaccine(s), duration of award, and total award value.

Annual awarded weighted average prices (WAPs) for each vaccine presentation will be posted on the UNICEF web-site.

3.20 DISCLOSURE OF PRICES

UNICEF reserves the right to disclose price information relevant to awards resulting from this RFP.

3.21 SAMPLES

Proposers should submit as part of their offer, three (3) samples for each vaccine offered of the following:

- Vaccine vial including closure and label
- Vaccine diluent, if applicable
- Vaccine dropper, if applicable
- Vaccine insert
- Inner box

If the samples provided are different from those submitted to WHO for pre-qualification, the differences should be explained.

Samples should be marked with the RFP number (stated on the front page of this document) and mailed to the address below, arriving no later than closing date of this tender.

UNICEF Supply Division
Oceanvej 10-12
2150 Nordhavn, Copenhagen
Denmark
Attention: Vaccine Centre, Contracts Specialist, Sonia Freitas Heurlin

3.22 RFP TERMS

This RFP, along with any proposal thereto, shall be considered the property of UNICEF and the proposals will not be returned to their originators.

In submitting the proposal, the Proposer agrees to acceptance of the decision of UNICEF as to whether the proposal meets the minimum requirements stated in this RFP; and the evaluation.

Information provided in the proposal will be treated as confidential unless otherwise noted by the Proposer.

3.23 DEBRIEFINGS

All Proposers receiving an award will be invited to a formal debriefing and award initiation meeting. Proposers not receiving an award may request a formal debriefing. During a debriefing, the strengths and weaknesses of the proposal may be discussed. Details concerning the evaluation results of other proposals will not be divulged other than outlined under 3.19 above.

3.24 RFP IN ELECTRONIC FORMAT

In order to assist with preparation of the proposal, the RFP will be provided in an electronic format (following the formal issuance of the RFP). All proposals however, must be returned to UNICEF in a sealed format, as defined in the Front Page.
4. TERMS AND CONDITIONS

4.1 PROGRAMMATIC FORECASTED VACCINE REQUIREMENTS

The requested requirements for Japanese Encephalitis vaccines for the period of 2015 and first two quarters of 2016 are:

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>2016</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catch-up</td>
<td>2,000,000</td>
<td>5,250,000</td>
<td>7,250,000</td>
</tr>
</tbody>
</table>

The key demand drivers listed at section 2.3 are to be considered.

4.2 MANDATORY TECHNICAL REQUIREMENTS

4.2.1 WHO PREQUALIFICATION

Only vaccines which are pre-qualified by WHO shall be considered for award.

The preferred product presentation is JE vaccine, lyophilised, 5 doses per vial; however, UNICEF also welcomes proposals for alternative product presentations.

4.2.2 PRODUCTION AND TESTING

The vaccines shall be produced and tested in conformity with the requirements of national legislation and the following recommendations established by the World Health Organization (WHO), or any subsequent revisions.

(g) Guide for inspection of manufacturers of biological products WHO/VSQ/97.03
(h) Regulation and licensing of biological products in countries with newly developing Regulatory Authorities (WHO Technical Report Series No. 858, 1995)
(j) Requirements for the use of animal cells as in vitro substrates for the production of biologicals (WHO Technical Report Series No. 878, 1998)
(k) Report of a WHO Consultation on Medicinal and other Products in relation to Human and Animal Transmissible Spongiform Encephalopaties. (WHO/BLG/97.2)
(m) Guidelines on regulatory expectations related to the elimination, reduction or replacement of thiomersal in vaccines, (WHO Technical Report Series No. 926, 2004)
(n) Guidelines on stability evaluation of vaccines (WHO/BS/06.2049 2006)
(p) WHO guidelines on nonclinical evaluation of vaccines (WHO Technical Report Series No. 927, 2005)

4.2.3 VACCINES

Vaccines must meet all the WHO recommended requirements and recommendations currently in force:


4.2.4 CHANGES IN FORMULATION, METHODS OR PROCESSES

Changes introduced in formulation, in methods of manufacturing in facilities or in any other aspects of production which might result in a change of safety and/or efficacy of vaccine, or which change the licensing agreement between the manufacturer and the National Regulatory Authority should be notified to WHO-PQT in accordance with WHO agreed timeframe. If manufacturing country regulations do not require approval of the changes by the NRA, then WHO-PQT Geneva should be consulted in a timely manner before changes are introduced.

Such changes may require additional activities by WHO to assure continued compliance with WHO requirements.

4.2.5 VACCINE SOURCE

All Proposers not producing the vaccine offered or their own vaccine bulk concentrate must indicate the source(s) for the vaccine quantity offered. Proposers shall provide evidence of the contractual agreements for the quantities being offered. Furthermore, the Proposer shall confirm that the quantities offered do not violate any contractual commitments made between the Proposer and the vaccine or bulk concentrate manufacturer.

4.2.6 NATIONAL REQUIREMENTS

It is recognized that, because of the special needs for vaccines for the developing countries, the specifications prepared for UNICEF by WHO may be more detailed than those given in the WHO Requirements, although they are not in conflict with them.

In those aspects where WHO GMP requirements are not detailed enough, other international guidelines shall be followed by the manufacturer – e.g. those of the European Union (EU), PDA (Parenteral Drug Association), and United States Pharmacopoeia (USP) – and appropriate justification for the choice shall be provided. In such cases, WHO will assess against the standard used.

4.2.7 LABELS AND PACKAGE INSERTS

Vaccine primary containers labels will be that agreed to by WHO during prequalification or as revised and approved by WHO and shall be affixed with water-resistant adhesive so that the labels do not become loose or fall off. Labels shall state the name of vaccine, name of manufacturer, place of manufacture, lot number, composition, concentration, dose and mode of administration, expiry
date, storage temperature, and number of doses per primary container. Expiry date and lot number shall be printed on each primary container in indelible ink. Adsorbed vaccines shall have the warning "DO NOT FREEZE" and "shake well before use” printed on the label.

The package insert will be that agreed by WHO during PQ or as revised and approved by WHO and shall be printed at least in English, French, Portuguese and Russian. Spanish and Arabic are optional. Separate inserts in the language appropriate for the country of destination will be welcome. In all inserts the following should be inserted under "Description of vaccines”. “The vaccine fulfils WHO requirements for….. (Name of vaccine)”.

Inserts shall contain at least the information in the WHO Model Insert enclosed for that vaccine. Any additional information provided by the manufacturer must not confuse or contradict WHO policy on the use of that vaccine. The current WHO model inserts are attached in Annex B.

Diluent primary container labels shall be affixed with water-resistant adhesive so that the labels do not become loose or fall off. They must be labelled with the same information as the label of the vaccine primary container, except that “Diluent for….vaccine” should replace the name of the vaccine.

4.2.8 CLOSURES
Vaccines in vial presentations shall be fitted with closures that conform to ISO standards 8362 (parts 2 through 7, as applicable). The container/closure system must be the same as submitted for prequalification.

4.2.9 VACCINE VIAL MONITORS (VVM)
Vaccine vials should be fitted with Vaccine Vial Monitors (VVMs). VVMs should comply with WHO PQS Performance Specification (WHO/PQS/E06/IN05.1) and in the PQS independent type-testing protocol (WHO/PQS/E06/IN05.VP.1). (Annex C).

4.2.10 RELEASE CERTIFICATION
Final acceptance of vaccines shall be subject to lot release by the National Regulatory Authority (NRA) of the country of manufacture or the NRA of Record agreed to with WHO during review for prequalification. Lot release certificates must be based as a minimum on review of the lot summary protocols.

Lot release certificates and Production and Control Summary Lot Protocols (according to WHO guidelines) will be provided upon request to consignees, UNICEF or WHO.

4.2.11 COMPLIANCE WITH TECHNICAL SPECIFICATIONS AND WHO REQUIREMENTS
Vaccines must meet all the WHO recommended requirements currently in force. It should be understood that if WHO requirements, which impact the products being supplied, are changed during the period of validity of the Arrangement, manufacturers will be required to implement such changes per agreed upon timeline following notification by WHO via UNICEF.

UNICEF reserves the right to reject any material which does not conform to the required specifications, and the awarded supplier shall forthwith at its own expense make good any material which has been rejected.

4.2.12 RETENTION SAMPLES AND TESTING
Samples of each batch of vaccine supplied under any resulting Arrangement shall be retained by the supplier for one year beyond expiry date.
These samples shall be provided, upon request, to WHO-PQT for testing.

Additionally reference and other materials required for testing should also be available to be supplied to WHO on request.

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Number of vials of finished product required (and appropriate diluent when needed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japanese Encephalitis</td>
<td>40</td>
</tr>
</tbody>
</table>

4.2.13 INTERRUPTION IN PRODUCTION AND/OR RELEASE PROCESSES

Any issues arising which may result in problems with production, quality control and/or release of vaccine should be communicated in a timely manner to UNICEF and WHO-PQT.

4.2.14 INSPECTION OF FACILITIES

The Supplier shall permit UNICEF and WHO, or their representatives as may be designated under notice to the Supplier, to have access to their manufacturing and warehouse facilities at all reasonable times to assess (or periodically reassess) the production and capacity, testing, packaging and storage of the goods, and shall provide reasonable assistance for such assessment including the provision of copies of manufacturing protocols, lot production records, test results or quality control reports.

UNICEF reserves the right to reject any Goods that do not conform to the required specifications.

Prequalification status is maintained until action is taken by WHO to revoke it. However, periodic reassessment by WHO is required. The frequency, scope and need for reassessment will be based on quality risk management principles.

The need for and scope of a site audit at time of reassessment will take into consideration the demonstrated history of regulatory inspection of the facility by the NRA (including supply of reports of GMP inspections by the NRA).

4.3 PACKING AND SHIPPING

Shipping arrangements shall be in accordance with the WHO "Guidelines on the International Packaging and Shipping of Vaccines", (WHO/IVB/05.23, http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_manufacturers_guidance/en/ ) or any subsequent revisions (Annex E). Detailed instructions regarding shipping and requirements for invoice and shipping documents shall be provided to the awarded Supplier as part of each Purchase Order.

Proposers should be informed that WHO is currently revising the 'Guidelines on the International Packaging and Shipment of Vaccines' (WHO/IVB/05.23, http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_manufacturers_guidance/en/ ). The revision is being conducted by WHO in consultation with industry. Any changes in requirements in the Guidelines will be implemented with a reasonable timeline.

All shipments of vaccines on behalf of UNICEF will be arranged through UNICEF designated freight forwarders, unless otherwise specified. The awarded Supplier shall contact and provide assistance and all documents to the UNICEF designated freight forwarder well in advance of the scheduled
delivery date. Any expected delay in delivery of the shipment shall be communicated to UNICEF and the UNICEF designated freight forwarder without delay.

The cost of packaging, packing, and all temperature monitoring devices must be included in the offered price. Manufacturers are requested to specify the price implications of temperature monitoring devices on the packing details sheet.

All containers, invoices and shipping documents are to bear the expiry dates of the vaccine and appropriate storage temperatures.

4.3.1 PACKING OF DILUENT FOR RECONSTITUTED VACCINES

The packed quantity per box of the diluent vials of a vaccine should be equal to the packed quantity per box of the vaccine vials.

4.3.2 GROSS WEIGHT and VOLUME

Proposers are required to state the total estimated gross weight and volume of the items offered as part of the PACKING DETAILS SHEET.

4.3.3 OVER LABELLING

Over labelling will only be accepted if the following criteria are met:
  a) The over labelling of the vaccine has been approved by the National Regulatory Authority of the producing country (released by NRA).
  b) UNICEF Supply Division is consulted prior to delivery.
  c) The receiving country agrees to receive the vaccine, and communicates this fact to the UNICEF Supply Division.

4.4 TRANSPORT AND STORAGE

4.4.1 TIME TEMPERATURE MONITORING DEVICE

In order to monitor the cold-chain during international transit to Government central stores, vaccines manufacturers are requested to include WHO PQS prequalified electronic shipping indicators (E06 category) in each and every shipping carton. Those devices meeting WHO requirements for international shipments can be found at the following site:


Detailed explanation of the temperature monitoring during international shipments can also be found in Chapter 2 (Temperature Monitoring Devices to be included in International Shipments) of the Guidelines on the International Packaging and Shipping of Vaccines, WHO/IVB/05.23. (Annex D)

4.4.2 VACCINE ARRIVAL REPORT (VAR)

Manufacturers will be requested to include a Vaccine Arrival Report together with the other shipping documentation in shipping box number one. The current VAR will be provided by UNICEF upon award. An example VAR is included in the Guidelines on the International Packaging and Shipping of Vaccines, WHO/IVB/05.23. (Annex D)
4.4.3 TEMPORARY STORAGE
The supplier agrees to properly store, from time to time and at no cost to UNICEF, finished products of vaccines for delivery at a later date. Storage of vaccines shall be under controlled environmental conditions to facilitate the conservation of the vaccines. The storage facilities shall comply with all national regulations for the storage of vaccines in force in the country where the storage facility is located.

4.4.4 DELIVERY PREPARATION LEAD-TIME
Proposers shall indicate, as part of the QUANTITATIVE PROPOSAL SHEET, the delivery preparation lead-time for each vaccine and presentation after receipt of an order. Delivery preparation lead-time includes time to complete administrative arrangements, including documentation, packing and marking. The maximum lead time should not exceed 30 days.

4.5 SHELF LIFE
Vaccine shall be supplied with the maximum shelf life possible consistent with current vaccine production technology and stability data. Unless separately authorised by UNICEF, the remaining shelf life at the time of dispatch shall not be less than the figures stated below:

Japanese Encephalitis vaccines: 18 months

4.6 ADVERSE EVENTS AND RECALLS
The manufacturer shall comply with all applicable laws, regulations and requirements regarding vaccine safety. The terms used surrounding adverse experiences shall have the meanings set forth in the International Conference on Harmonization (ICH) of Technical Requirements of Pharmaceuticals for Human Use E2A.

The manufacturer shall be solely responsible for global pharmacovigilance activities regarding the Vaccine including but not limited to: adverse experience (AE) or adverse drug reaction (ADR) reporting including literature review and associated reporting; AE/ADR follow-up reporting; preparation and submission of all safety reports to applicable regulatory agencies, as required; periodic submissions; labelling modifications; risk management; safety monitoring and detection and coordinating and implementing safety measures.

The manufacturer shall promptly inform WHO-PQT and UNICEF of serious issues (actual or alleged) regarding vaccine safety and shall provide them with information sufficient to consider such issues. WHO and UNICEF shall promptly notify the supplier of serious adverse events involving supplier’s vaccine of which they become aware.

If any circumstance or event may require or make reasonably appropriate any recall or withdrawal of vaccine or any field alert regarding the vaccine, the manufacturer shall immediately notify WHO-PQT and UNICEF and other appropriate entities. When a recall, withdrawal or field alert is required or appropriate, the manufacturer shall take all appropriate actions and shall bear all associated expenses.

4.7 FINANCIAL AND COMMERCIAL REQUIREMENTS

4.7.1 SUPPLIER’S REPRESENTATION
The awarded manufacturer represents and warrants that it has the personnel, experience, qualifications, facilities and all other skills and resources necessary to perform its obligations under
the resulting LTA.

4.7.2 EXPERIENCE IN VACCINE SUPPLY & DELIVERY
The Proposer shall demonstrate proven experience and qualification in the supply and delivery of the vaccines being proposed. In addition to the following information, the Proposer may supply other information as deemed appropriate:

- Number of years of production and delivery by vaccine (quantities);
- Customer reference list by vaccine. This should include customer contact names and communication information (phone/e-mail/fax) (applicable to all suppliers with less than 3 years’ experience as an UNICEF supplier); and
- Names of regulatory bodies where products are registered, and date of original registration.

4.7.3 PAST PERFORMANCE RECORD
Proposers not previously supplying UNICEF shall demonstrate that they have been able to provide on time deliveries and maintained production schedules, and the time period over which the on time delivery performance has been measured. They shall also advise UNICEF of the annual production quantity.

4.7.4 REASONABLE PROPOSED QUANTITY
If the proposed quantity is disproportional to past years’ annual production quantity, the Proposer shall demonstrate that they are able to supply the quantity being proposed by them to UNICEF during the quoted timeframe. They shall also advise UNICEF of the current annual production quantity. WHO-PQT will be evaluating the proposed quantity as part of the technical evaluation.

4.7.5 MONTHLY ALLOCATION REPORTING
Upon any resultant award, the supplier agrees to provide UNICEF with a monthly allocation report, listing the following for each vaccine presentation:

- the total quantities forecasted for delivery during the next six-month period;
- total quantity in stock with NRA release;
- total quantity in stock pending NRA release;
- the total quantities in production; and
- any additional relevant information the Parties agree to include.

For former or current suppliers to UNICEF, adherence to the monthly allocation reporting will be evaluated.

4.7.6 MEDIUM AND LONG TERM PLANS
Proposer is requested to provide information on their medium and long term plans for production of the vaccine(s) being offered, or on vaccines that may be offered in the future, including an overview of business factors affecting the decision to produce the vaccine at the quantities offered.

4.7.7 CURRENCY OF PROPOSAL
The currency of the proposal shall be US Dollars.

4.7.8 AFFORDABILITY OF PRICES OFFERED
The Proposer is requested to provide information on factors that influence the pricing offered to UNICEF including the basis for any quantity-based pricing. Any price increase over previous years’ pricing should be explained.

UNICEF believes in paying a price that is affordable to Governments and Donors and a price that
reasonably covers manufacturers’ minimum requirements.

4.7.9 INCOTERMS AND UNIT PRICING
Unit pricing is to be provided on a FCA nearest international airport basis (INCOTERMS 2010). The name and location of the international airport is to be specified.

4.7.10 VVM and UNIT PRICING
UNICEF requests vaccines with VVM.

Unit pricing is to include the price of VVM, however, the manufacturer shall also provide the price addition, if any, that inclusion of the VVM represents. If a manufacturer has not implemented VVM but has a plan to do so, unit pricing shall be offered without VVM with a price increment which is to be included in the unit price when VVM becomes implemented.

4.7.11 MINIMUM QUANTITY GUARANTEES AND FIRM CONTRACTING
UNICEF welcomes alternative proposals conditional upon firm UNICEF commitment to defined quantities. Such proposals will be evaluated against their utility in reaching the specific objectives of the tender. Any firm UNICEF commitment would be subject to funding availability as well as other agreed upon conditions, including reciprocity clauses (e.g. liquidated damages).

During the evaluation of such a proposal, UNICEF may share a summary of the proposal with a potential third-party funder. Also, during any clarifications of such a proposal, the third party may be requested by UNICEF to participate in such discussions.

4.7.12 EVIDENCE OF COMPLIANCE
No payment, acceptance or concurrence shall be construed as evidence that any matter or thing is complete, satisfactory or in accordance with the awarded supplier’s obligation, and the awarded supplier shall thereby not be relieved or discharged from performing any obligation under the Arrangement.

4.7.13 INDEMNIFICATION
Within the framework of all applicable privileges and immunities, the Proposer agree to indemnify, defend and hold harmless UNICEF, each of the Governments receiving the vaccines, and all parties making a financial contribution to the purchase of the vaccines (together, the "Indemnified Parties" and each an "Indemnified Party") from and against all claims, damages, losses, costs and expenses (including reasonable legal fees) arising out of or related to the purchase, distribution and use of the vaccines supplied under these arrangements other than, in respect of each Indemnified Party, those attributable to any fault or negligence of that Indemnified Party. UNICEF shall promptly give notice to the Proposer of any such claims, damages, losses, costs and expenses brought to its attention (including those brought to its attention by another Indemnified Party) and shall cooperate in a reasonable manner in their investigation and assessment. The obligations under this clause do not lapse upon termination of any procurement arrangement resulting from this RFP.

4.7.14 WARRANTIES
Unless specifically otherwise agreed by the Parties in writing, in addition to and without limitation of any other warranties stated in or arising under the Procurement Arrangement, the supplier warrants and represents that the goods, including all packaging and packing thereof, conform to the specifications of the Procurement Arrangement, are fit for the purposes for which such goods are ordinarily used and for the purposes expressly made known in writing by UNICEF to the supplier, and shall be of even quality, free from faults and defects in design, material, manufacturer and workmanship. If the supplier is not the original manufacturer of the goods, the Proposer shall provide all manufacturers’ warranties in addition to any other warranties hereunder.
The successful propose will be required to acknowledge that:
(a) UNICEF may further distribute the goods supplied to its Programme partners, including procurement services customers;
(b) The benefit of any warranties provided and liabilities entered into with UNICEF, shall be passed on by UNICEF to its Programme partners, including Procurement Services customers.

4.7.15 INTELLECTUAL PROPERTY INFRINGEMENT
The Proposer warrants that the use or supply by UNICEF of the goods offered to UNICEF under this RFP does not infringe any patent, design, trade name or trademark. In addition, the Proposer shall, pursuant to this warranty, indemnify, defend and hold UNICEF and the UNICEF-contracted parties harmless from any actions or claims brought against UNICEF or the UNICEF-contracted parties pertaining to the alleged infringement of a patent, design, trade-name or trade-mark arising in connection with the goods sold under any resulting LTA.

4.7.16 FULL RIGHT TO USE/SELL ITEMS
The awarded supplier warrants that it has not and shall not enter into any other agreement or arrangement that restrains or restricts UNICEF or the recipient Governments’ rights to use, sell, dispose of or otherwise deal with any item acquired under the Long Term Arrangements.

The awarded supplier further warrants that they hold the necessary marketing rights for supply of products for the purposes specified in this Request and the supplier’s offer. The supplier is required to highlight in their offer any limitations in the supplier’s marketing right restricting use of the offered product.

4.7.17 FORCE MAJEURE
For any resulting LTA from this RFP: If either Party is prevented by Force Majeure from fulfilling its obligations under the LTA, it shall not be deemed in breach of such obligations. The said Party shall use all reasonable efforts to mitigate consequences of force majeure. At the same time, the Parties shall consult with each other on modalities of further execution of the LTA. 'Force Majeure' as used in the LTA will mean natural catastrophes such as, but not limited to, earthquakes, floods, cyclonic or volcanic activity; war (whether declared or not); invasion, act of foreign enemies, rebellion, terrorism, revolution, insurrection, military or usurped power, civil war, riot, commotion, disorder; ionizing radiation or contaminations by radioactivity; pandemics or disease epidemics; other acts of a similar nature or force.

4.8 EVALUATION OF PROPOSALS AND BASIS FOR AWARD

4.8.1 PROPOSAL EVALUATION METHOD and EVALUATION CRITERIA
The merits of each proposal will be evaluated to assess its ability to support the objectives of this tender as outlined in section 2.2.

4.8.2 EVALUATION METHODOLOGY
The evaluation consists of two main reviews:
1) Review of Mandatory Requirements, and
2) Evaluation of Quantitative and Qualitative content of the proposal.

4.8.2.1 REVIEW OF MANDATORY REQUIREMENTS
Technical Mandatory Requirements will be evaluated by WHO. All other Mandatory Requirements will be evaluated by UNICEF.

For an offer to be eligible for an award, all Mandatory Requirements must be met. Please refer to Section 3.2 for further information.
If the proposal is deemed interesting in its potential ability to support the objectives of this tender and meets the Mandatory Technical Requirements, except that the product is not WHO pre-qualified, UNICEF will proceed as outlined in Section 4.8.4.

4.8.2.2 EVALUATION OF QUANTITATIVE AND QUALITATIVE CONTENT
During this evaluation, the nature of the commercial proposal will be studied and compared to the evaluation criteria. In order to obtain to what extent a proposal is found satisfactory, all quantitative data will be evaluated together with the qualitative data to determine how the factors presented in each proposal will support the objectives as per Section 2.2.

4.8.3 BASIS FOR AWARD
Upon evaluation of all proposals, taking into consideration the actual market situation for the vaccine, the forecasted quantities will be awarded to manufacturers in accordance with the objectives of this tender. Some of the forecasted quantities may be left unawarded if UNICEF believes this will help achieve the objectives of the tender.

The below table lists the evaluation criteria that will determine the basis for award:

**Overview of Quantitative Information**

<table>
<thead>
<tr>
<th>Objective</th>
<th>Evaluation criteria</th>
</tr>
</thead>
</table>
| Affordable price                              | • Price FCA nearest international airport, including  
|                                                |   - Cost of approved wastage factor for the proposed vial size  
|                                                |   - Cost of international transport  
|                                                | • Validity period of proposals  
|                                                | • Payment terms  
|                                                | • Quantity offered  
|                                                | • Conditions of quantity offered  
|                                                | • Demonstration of capacity to provide quantities offered; possible effects of quantities offered on other vaccine presentations  
|                                                | • Lead-time  
|                                                | • Total production capacity  
|                                                | • Product mix offered  
|                                                | • Vial/ampule size, presentation and formulation  
|                                                | • Shelf life  
|                                                | • Weight and volume, including whether meets WHO recommendation  
| Securing stable and sufficient supply         |
Overview of Qualitative Information

<table>
<thead>
<tr>
<th>Objective</th>
<th>Evaluation Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affordable price</td>
<td>• Prices compared to other offers</td>
</tr>
<tr>
<td></td>
<td>• Factors that influence the pricing offered to UNICEF and the cost to GAVI</td>
</tr>
<tr>
<td>Securing stable and sufficient supply</td>
<td>Long Term plans for production of the vaccine being offered,</td>
</tr>
<tr>
<td></td>
<td>including overview of business factors affecting the decision to produce the vaccine at the quantities offered, and potential to ensure the vaccine is made available as proposed</td>
</tr>
<tr>
<td></td>
<td>Account management resources (organizational charts with names) and customer service capabilities including:</td>
</tr>
<tr>
<td></td>
<td>• Accurate and reliable planning and forecasting, including</td>
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<tr>
<td></td>
<td>monitoring NRA release, efficient order processing, accurate and</td>
</tr>
<tr>
<td></td>
<td>complete documentation, close production follow-up</td>
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<tr>
<td></td>
<td>• Willingness to include a Vaccine Arrival Report as part of shipping documents</td>
</tr>
<tr>
<td>Experience in vaccine supply and delivery:</td>
<td>• Number of years of production and delivery (quantity)</td>
</tr>
<tr>
<td></td>
<td>• Customer reference list (applicable to all suppliers with less than</td>
</tr>
<tr>
<td></td>
<td>3 years’ experience as a UNICEF supplier)</td>
</tr>
<tr>
<td></td>
<td>• Number and names of regulatory bodies where products are registered and date of original registration</td>
</tr>
<tr>
<td></td>
<td>• Proven reliable forecasting of supply</td>
</tr>
<tr>
<td>Past performance record:</td>
<td>• Realistic lead-time offered</td>
</tr>
<tr>
<td></td>
<td>• Proven capacity to supply offered and forecasted quantities</td>
</tr>
<tr>
<td></td>
<td>• On-time deliveries</td>
</tr>
<tr>
<td></td>
<td>• Reliable and firm forecasted supply</td>
</tr>
<tr>
<td></td>
<td>• Realistic quantity offered</td>
</tr>
<tr>
<td></td>
<td>• Accurate Monthly allocation reporting (for current suppliers)</td>
</tr>
<tr>
<td></td>
<td>• Agreement to store vaccines on a need basis as well as under what</td>
</tr>
<tr>
<td></td>
<td>circumstances (ability to keep buffer stock)</td>
</tr>
<tr>
<td></td>
<td>• Maintained quality level per WHO requirements</td>
</tr>
<tr>
<td></td>
<td>• Adherence to current packing and shipping requirements</td>
</tr>
<tr>
<td></td>
<td>• Initiative to resolve problems in a satisfactory and fast manner</td>
</tr>
<tr>
<td></td>
<td>• Support to AEFI reporting</td>
</tr>
</tbody>
</table>

If a proposer has not been a supplier to UNICEF previously, UNICEF reserves the right to introduce the supplier incrementally during the award period and assess its performance closely.

4.8.4 PROPOSALS FOR PRODUCTS NOT YET WHO PRE-QUALIFIED

If the Proposer is not WHO pre-qualified for the product offered, the Proposal must include a detailed plan on the timeline to obtain WHO pre-qualification. The timeline should include information regarding the product and plans for manufacturing and licensing:
a) Product Development: Status and plans, including source of bulk antigens to be used.
b) Clinical Trials: Trials conducted so far and planned, with timelines.
c) National Regulatory Registration: Status and plans for registration, including NRA that would be responsible for release of finished product and planned product presentations.
d) File submission to WHO: Status and plans.

If the manufacturer’s Proposal was deemed of interest to UNICEF, UNICEF will advise the manufacturer of such and will request that UNICEF be kept informed about the progress of the submitted timeline.

If the proposed vaccine obtains WHO pre-qualification during the award period and upon confirmation that the mandatory requirements of the RFP are met, UNICEF would consider awarding a quantity to the manufacturer under one or more of the following conditions:

UNICEF is facing a monopoly situation or a near monopoly situation;
1. UNICEF is facing a monopoly situation or a near monopoly situation;
2. Lack of performance of current supplier(s);
3. Insufficient supply from current supplier(s);
4. If it meets the specific objectives of the tender; or
5. To meet unallocated demand quantities.

The quantities considered for award would be those not met under established contracts or quantities that could be reallocated from existing arrangements after negotiation with the corresponding suppliers.

4.9 SPECIAL TERMS AND CONDITIONS

4.9.1 UNETHICAL BEHAVIOUR
UNICEF strictly enforces a policy of zero tolerance concerning unethical, unprofessional or fraudulent acts of UNICEF Proposers. Accordingly, any registered Proposer that is found to have undertaken unethical, unprofessional or fraudulent activities will be suspended or forbidden from continuing business relations with UNICEF.

4.9.2 CORRUPT AND FRAUDULENT PRACTICES
UNICEF requires that all Proposers associated with this Request for Proposal observe the highest standard of ethics during procurement and execution of the work. In pursuance of this policy UNICEF

a) Defines for the purpose of this provision the terms set forth as follows:
   i. Corrupt practice means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in the execution of a contract, and
   ii. Fraudulent practice means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the client, and includes collusive practice among Proposers (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the client of the benefits of free and open competition;

b) Will reject a proposal for award if it determines that the selected supplier/contractor has engaged in any corrupt or fraudulent practices in competing for the contract in question;

c) Will declare a Proposer ineligible, either indefinitely or for a stated period of time, to be awarded a UNICEF-financed contract if at any time it determines that it has engaged in any corrupt or fraudulent practices in competing for, or in executing a UNICEF-financed contract.
4.9.3 DISCLOSURE OF SANCTIONS OR TEMPORARY SUSPENSION
Only suppliers found to be responsible or conditionally responsible are eligible to be awarded UNICEF contracts and/or to bid on UNICEF solicitations. To be deemed a responsible supplier with whom UNICEF will conduct business, a supplier should not be suspended, debarred, or otherwise identified as ineligible by the World Bank Group, any of its member governments or any other International or UN Organization. Suppliers are therefore required to disclose to UNICEF whether they are subject to any sanction or temporary suspension imposed by the World Bank Group, any of its member governments or any other International or UN Organisation.

4.9.4 OFFICIALS NOT TO BENEFIT
The Proposer warrants that no official of UNICEF or the United Nations has received or will be offered by the Proposer any direct or indirect benefit arising from this Request for Proposal or the award thereof. The Proposer agrees that breach of this provision is a breach of an essential term of the Request for Proposal.

4.9.5 GUIDELINES ON GIFTS AND HOSPITALITY
Proposers shall not offer gifts or hospitality to UNICEF staff members. Recreational trips to sporting or cultural events, theme parks or offers of holidays, transportation, or invitations to extravagant lunches or dinners are also prohibited.

4.9.6 MOST FAVOURED NATION
If at any time during the validity period of the LTA, the awarded supplier offers to sell the vaccine at a price lower than the price effective under the LTA, the awarded supplier shall offer the same price to UNICEF for the remaining validity period of the LTA.

4.9.7 GENERAL TERMS AND CONDITIONS
The UNICEF General Terms and Conditions attached to this bid (Annex A) shall apply to any resulting LTA and related Purchase Orders. In the case of any inconsistencies, the following order of precedence shall prevail:

(a) The Purchase Order;
(b) The LTA.
5. ANSWER SHEETS

PROPOSAL FORM

PROPOSAL FORM must be completed, signed and returned to UNICEF. Proposals must be made in accordance with the instructions contained in this REQUEST. UNICEF shall not pay any costs incurred in the preparation or submission of proposals.

TERMS AND CONDITIONS OF LONG TERM ARRANGEMENT
Any Long Term Arrangement resulting from this REQUEST shall contain the UNICEF General Terms and Conditions and any other terms and conditions specified in this REQUEST.

INFORMATION
Any request for additional information regarding this REQUEST must be forwarded in writing to the attention of Contracts Specialist, Ms. Sonia Freitas Heurlin (email: sfreitas@unicef.org) with specific reference to this REQUEST, so that the query may be answered in the normal course of business.

The Undersigned, having read the Instructions to Proposers of this REQUEST RFP-DAN-2014-501825 and all related documents hereby offers to supply the goods and contributions to meet the overall objectives sought in accordance with any specifications stated and subject to all Terms and Conditions set out or specified in this REQUEST.

Signature:_________________________________________________

Date: ____________________________________________________

Name & Title:______________________________________________

Company:_________________________________________________

Postal Address:____________________________________________

Tel No:___________________________________________________

Fax No:___________________________________________________

E-mail:___________________________________________________

Validity of Offer:__________________________________________
Please include a response to the following.

1. Does each product offered have WHO pre-qualification?

2. If the answer to the above is “No”, then please provide a detailed plan on your timeline to obtain WHO pre-qualification. The timeline should include information regarding the product and plans for manufacturing and licencing, including the key milestones below. A timeline should be provided for each product offered that is not pre-qualified.
   a) Product Development: Status and plans, including source of bulk antigens to be used;
   b) Clinical Trials: Trials conducted so far and planned, with timelines;
   c) National Regulatory Registration: Status and plans for registration, including NRA that would be responsible for release of finish product and planned product presentations; and
   d) File submission to WHO: Status and plans.

3. Please provide your United National Global Marketplace (UNGM) registration number___________

   If your company has not yet registered through the UNGM, please submit an application through the UNGM website at http://www.ungm.org under http://www.ungm.org/Registration/RegisterSupplier.aspx.

   Instructions are provided on the site.

4. Have you provided audited financial statements to UNICEF in the past 12 months?

   If not, please proceed as per clause 3.14.2.
QUALITATIVE PROPOSAL SHEET

Please provide response to the following in your proposal together with any other information deemed relevant.

1. Advise the number of years that your company has of production and delivery of the offered product(s).

2. For manufacturers 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.

3. Provide organizational charts and names of the responsible persons within each following department: Production, Quality, Governmental Affairs, Shipping/Logistics, Sales and Marketing, specifying the name(s) of the person(s) who will be the primary contact for UNICEF.

4. Provide a list of the names of regulatory bodies where your products are registered as well as original date of registration.

5. Given that UNICEF has requested prices that are affordable to the poorest country governments and donors please indicate factors influencing your price setting.

6. Please include in your proposal your total annual production capacities for bulk and final filled product for each offered vaccine. If the vaccine bulk is not produced by the Proposer, please advise of source of bulk, and evidence of contractual access to bulk.

7. Please provide information on your medium and long term plans for production of the vaccine being offered, including an overview of business factors effecting the decision to produce the vaccine at the quantities offered to UNICEF.

8. Please advise whether the production of any of the vaccines offered effects the production, or potential production, of another vaccine being offered by your company. If yes, please advise which vaccines.

9. 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 measurements taken for improvement.

10. Please indicate the capacity and willingness to store vaccines on a need basis and maintain a buffer stock, indicating any conditions that may apply.
QUANTITATIVE PROPOSAL SHEET

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers the supply of the vaccine in quantities, at prices and within the number of days indicated below:

Japanese Encephalitis vaccine, lyophilised, 5 doses per vial
Quantity: 7,250,000 million doses

<table>
<thead>
<tr>
<th>Timing of Offers</th>
<th>Monthly/ quarterly Quantity</th>
<th>Unit Price per vial FCA Int'l airport USD</th>
<th>Conditions/ Discounts*</th>
<th>Total Amount (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,000,000 million doses for 2015</td>
<td>Insert data on Page 29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5,250,000 million doses for 2016</td>
<td>Insert data on Page 29</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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:

INCOTERMS (2010) FCA Nearest International Airport (Name Airport): ______________

Vaccine Vial Monitors: Yes: _____ No: _____

Advise price implication for VVM: ___________________________

Total production capacity: ___________________________

Normal shelf life at time of shipment: __________________

Vaccination schedule: ___________________________

Delivery preparation lead time required for preparation of delivery (administration of order, packing, markings, etc.) within above-mentioned schedule: ________________ days.

Country of Origin: ______________

WHO pre-qualified product: Yes:_____ No:___

Additional comments:
QUANTITATIVE PROPOSAL SHEET – for alternative proposals/product presentations

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers the supply of the vaccine in quantities, at prices and within the number of days indicated below:

<table>
<thead>
<tr>
<th>Timing of Offers</th>
<th>Monthly/quarterly Quantity</th>
<th>Unit Price per vial FCA Int’l airport USD</th>
<th>Conditions/Discounts*</th>
<th>Total Amount (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,000,000 million doses for 2015</td>
<td>Insert data on Page 29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5,250,000 million doses for 2016</td>
<td>Insert data on Page 29</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: UNICEF also welcomes proposals for alternative product presentations.

* 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:

INCOTERMS (2010) FCA Nearest International Airport (Name Airport): ______________

Vaccine Vial Monitors: Yes: ______ No: _____

Advise price implication for VVM: __________________

Total production capacity: __________________

Normal shelf life at time of shipment: ______________

Vaccination schedule: __________________

Delivery preparation lead time required for preparation of delivery (administration of order, packing, markings, etc.) within above-mentioned schedule: ________________ days.

Country of Origin: _______________

WHO pre-qualified product: Yes: ____ No: ___

Additional comments:
## OFFERED QUANTITIES (DOSES) AVAILABLE FOR PROCUREMENT BY UNICEF SHEET

### PLEASE ENTER QUANTITIES IN DOSES (INDICATIVE)

<table>
<thead>
<tr>
<th>Doses</th>
<th>5 dose presentation</th>
<th>Other presentation</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>3rd/4th Quarter 2014</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st Quarter 2015</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd Quarter 2015</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd Quarter 2015</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4th Quarter 2015</td>
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<td><strong>Total:</strong></td>
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PACKING DETAILS SHEET

The Proposer is requested to provide UNICEF with packing details for each vaccine product offered using this SHEET.

A. Name of Vaccine: ________________________________

B. Please advise if this vaccine is packed using ice packs or 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.

C. Please specify type of Time Temperature Monitoring Device: ______________

D. Standard EXPORT Packing Dimensions and Weight:

<table>
<thead>
<tr>
<th></th>
<th>Vaccine</th>
<th>Diluent</th>
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</thead>
<tbody>
<tr>
<td>Total no. of Doses</td>
<td></td>
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<tr>
<td>Total no. of Vials</td>
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<td>Dimensions: Length</td>
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<td>Number of inner cartons</td>
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E. Standard INNER CARTON Packing Dimensions and Weight:

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COMMERCIAL TERMS SHEET

In compliance with the Instructions to Proposers of this Request for Proposal and all sections hereto, the undersigned offers the supply of the vaccine under the conditions and in quantities, at prices and within the number of days as indicated in the QUALITATIVE PROPOSAL SHEET AND QUANTITATIVE PROPOSAL SHEET(S); and the undersigned accepts in full the TERMS and CONDITIONS.

Signature:________________________________________________

Date:____________________________________________________

Name & Title:______________________________________________

Company:_________________________________________________

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 are to be defined below (additional pages may be attached):