REQUEST FOR PROPOSAL

UNITED NATIONS CHILDREN'S FUND (UNICEF)
wishes to receive proposals for

2018-2020 Measles Containing Vaccines

FOR DELIVERY DURING THE PERIOD OF 1st JANUARY 2018 TO 31st DECEMBER 2020

RFP-DAN-2017-502616 **19th October 2017**

SEALED PROPOSALS must be received at the following address up to **11.00 AM (Copenhagen time) on 16th November 2017.**

UNITED NATIONS CHILDREN'S FUND (UNICEF)
Attention: BID SECTION RFP-DAN-2017-502616
Oceanvej 10-12
2150 Nordhavn, Copenhagen
Denmark
Tel +45 4533 5500

EMAILED PROPOSALS must be sent to the email supplybid@unicef.org up to 11.00 AM (Copenhagen time) on 16th November 2017. Proposals sent to a different email will be INVALIDATED, even if received before the stipulated deadline.

PROPOSALS RECEIVED IN ANY OTHER MANNER WILL BE INVALIDATED

Prepared by: Ms. Michaela Briedova, Contracts Officer

Approved by:

P.P Ms. Heather Deehan
Chief, Vaccine Centre
Supply Division, UNICEF

Ms. Katinka Rosenbom
Chief, Contracting Centre
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Ms. Etleva Kadilli
Director, a.i.
Supply Division, UNICEF

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1. PURPOSE

The purpose of this Request for Proposal (RFP) is to establish Long Term Arrangement(s) (LTA) for the supply of Measles Containing Vaccines through UNICEF for the period of January 2018 through December 2020.

The following vaccines, referred to as Measles Containing Vaccines (MCV) are included in this RFP:

- Measles monovalent vaccine (Measles)
- Measles-Rubella vaccine (MR)
- Measles-Mumps-Rubella vaccine (MMR)

As a result of this RFP, UNICEF will work with selected manufacturers to establish supply arrangements that best meet the objectives of this solicitation. These supply arrangements will provide the basis upon which Purchase Orders will be made for specific vaccine deliveries throughout the period and will facilitate access for routine immunization programmes, planned supplementary immunization activities and for outbreak response.

2. BACKGROUND

2.1 PROGRAMMATIC UPDATE

Measles is one of the leading killers of children worldwide, yet, measles as well as rubella are easily preventable with a safe and effective vaccine. World Health Organization (WHO) recommends that children receive two doses of MCV[1]. The WHO also recommends that measles and rubella efforts be combined.

Since the formation of the major global partnership to tackle the measles deaths and rubella related complications, Measles and Rubella Initiative (M&RI), significant progress has been made. M&RI and its partners have provided 16 years of support to countries that has helped save millions of lives. Thanks to support from the M&RI and partners including Gavi, the Vaccine Alliance, Measles vaccine saved an estimated 20.3 million lives, with more than 2 billion doses of Measles vaccine delivered to children in 88 countries in just over a decade. With this ongoing support, Measles vaccination coverage increased to 85% globally, reduced measles deaths by 79%[2] and as of September 2016, the Americas became the first Region to be declared free of endemic measles and rubella.

The M&RI's 2012-2020 strategy[3] focuses on the implementation of five core components:

1. Achieve and maintain high levels of population immunity by providing high vaccination coverage with two doses of Measles- and Rubella-containing vaccines.
2. Monitor disease using effective surveillance, and evaluate programmatic efforts to ensure progress.
3. Develop and maintain outbreak preparedness, respond rapidly to outbreaks and manage cases.
4. Communicate and engage to build public confidence and demand for immunization.
5. Perform the research and development needed to support cost-effective operations and improve vaccination and diagnostic tools.

The engagement of Gavi, the Vaccine Alliance in the Measles Programme dates back to 2004. The new Measles and Rubella strategy[4], which came to effect in 2016 focuses on increasing country ownership, strengthening routine immunization, and ensuring long-term programmatic and financial sustainability. The Measles and Rubella Strategy provides comprehensive support for the following immunization activities:

- MR vaccine Catch up (introduction) campaigns, targeting children aged 9 months to 14 years, when followed by or coinciding with MR routine introduction,
- Measles and MR vaccine introduction into routine immunization (Measles as second dose, MR as first and/or second dose),

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[1] http://www.who.int/immunization/policy/Immunization_routine_table1.pdf
[2] http://measlesrubellainitiative.org/learn/the-solution/
[3] http://apps.who.int/iris/bitstream/10665/44855/1/9789241503396_eng.pdf
[4] http://www.gavi.org/support/nvs/measles-rubella/

- Measles and MR vaccine follow up campaigns with focus on children up to 5 years of age,
- Outbreak response fund managed by the M&RI to further support countries that cannot respond to significant outbreaks fast enough with local funding.

2.2 PROCUREMENT OBJECTIVES AND PRINCIPLES

The objectives of this solicitation are:

- To ensure continued Vaccine Security, defined as timely, sustained, and uninterrupted supply of affordable vaccines of assured quality
- To achieve prices for MCV that are affordable for countries and donors
- To improve the health of the supply market

UNICEF's vaccine procurement principles listed below, were reviewed in the context of the current market situation and programmatic objectives and have been deemed relevant and necessary to maintain Vaccine Security:

- A healthy industry is vital to ensure uninterrupted, sustainable supply of affordable vaccines of assured quality;
- Procurement from multiple suppliers for each vaccine presentation;
- Procurement from manufacturers in developing countries and industrialized countries;
- Paying a price that is affordable to Governments and Donors and a price that reasonably covers manufacturers minimum requirements;
- Providing manufacturers with accurate and long-term forecasts and manufactures providing UNICEF with accurate and long-term production plans;
- As a public buyer, providing grants to manufacturers is not the most effective method of obtaining capacity increases;
- The option to quote tiered pricing should be given to manufacturers.

UNICEF will continue to make efforts to support manufacturers' focus on affordability of vaccines by tendering for supply covering a multi-year period and continuously working on forecasting of short and long term requirements.

As the result of the RFP-DAN-2017-502616, UNICEF aims at establishing LTAs with the selected supplier(s) for the period from 1st January 2018 through 31st December 2020.

2.3 DEMAND FORECAST

2.3.1 Tender forecast

There are three streams of demand for MCV through UNICEF: routine immunization programs, campaigns (catch up/introduction campaign and follow up) and outbreak response.

UNICEF is requesting offers from manufacturers to fulfil the demand forecast during 2018 through 2020:

Tender forecast 2018-2020, in millions of doses				
Vaccine	**Type of demand**	**2018**	**2019**	**2020**
Measles-10	Routine needs	70	70	65
	Follow up campaigns	65	35	5
	TOTAL	**135**	**105**	**70**
Measles-5	**Routine needs**	**5**	**5**	**5**
Total Measles		**140**	**110**	**75**
MR-10	Routine needs	60	65	70
	India, GAVI funded, Catch up	111.5		
	Follow up campaigns	35	30	15
	Catch up campaigns	25	35	95
	TOTAL	**231.5**	**130**	**180**
MR-5	**Routine needs**	**10**	**15**	**20**
Total MR		**241.5**	**145**	**200**
MMR-1	Routine needs	1	1	1
MMR-2	Routine needs	3.5	2.5	2.5
MMR-5	Routine needs	8	8	8
MMR-10	Routine needs	8	8	8

Outbreak Response

In order to facilitate the effective response to outbreaks and emergencies, UNICEF wishes to maintain immediate access to 1 million doses of Measles vaccine and 500,000 doses of MR vaccine at all times. Such quantities should be available for deployment to areas experiencing outbreaks or other emergencies within 72 hours from receipt of UNICEF Purchase Order. Proposers are requested to confirm their willingness and ability to maintain 1 million doses of Measles vaccine and/or 500,000 doses of MR vaccine as part of their proposal against this tender.

2.3.2. Elements of MCV demand forecast

UNICEF is procuring MCV on behalf of on average 75 countries per year, with funding from Gavi, the Vaccine Alliance, UNICEF's Procurement Services on behalf of countries, UNICEF Programme and M&RI.

Accurate forecasting is the foundation of Vaccine Security. UNICEF recognizes the importance of accurate forecasting both for the demand forecasts provided by UNICEF to manufacturers and the supply availability forecasts provided by manufacturers to UNICEF.

The demand forecast is based on inputs received through yearly forecasting exercise undertaken by UNICEF in collaboration with government partners, ongoing communication with countries and programme partners, and work taking place within M&RI partnership and Gavi, the Vaccine Alliance. The demand forecast is continuously maintained by UNICEF and regularly shared with awarded suppliers at least on monthly basis.

2.3.2.1. Measles and MR Vaccine

Demand for Measles vaccine is expected to decrease as countries introduce Rubella vaccine. However, slower uptake of the MR vaccine resulting in potential delay or postponement of MR introduction will increase demand for Measles vaccine. If countries delay MR introduction, depending on country specific context, they may instead conduct a Measles follow-up campaign. Furthermore, the country's routine demand would in this case continue to be with Measles vaccine. Countries' programmatic readiness to introduce MR vaccine, their eligibility to receive support from Gavi as well as timing and quality of their application to Gavi will influence the timing of the introduction.

2.3.2.2. MMR Vaccine

Routine mumps vaccination is recommended in countries with well established, effective childhood vaccination programme and the capacity to maintain high level vaccination coverage with measles and rubella and where the reduction of mumps incidence has been determined to be a public health priority.

On average 26 countries regularly procure their MMR requirement partly or in full through UNICEF. A subset of the countries have indicated strong preference for a particular mumps strain and strictly enforce vaccine registration requirements. While this tender forecasts requirements for MMR vaccine with Jeryl Lynn and Leningrad-Zagreb mumps strain, manufacturers with other mumps strains are encouraged to participate in this tender.

Countries' preference for mumps strain and presentation:

- **MMR-1:** Forecasted demand from countries with preference for the 1 dose vial presentation, without preference for specific mumps strain.
- **MMR-2:** Forecasted demand from countries with specific preference for Jeryl Lynn mumps strain. The demand may be satisfied through supply of other vial size presentations.
- **MMR-5/MMR-10:** Forecasted demand from countries with preference for the specific vial presentation, but without preference for any specific mumps strain.

MMR Vaccine for Ukraine:

Ukraine has indicated a preference for vaccine with Jeryl Lynn mumps strain and has a yearly forecasted demand for routine immunization at approximately 1.4 million doses. Due to increased incidence of measles in Ukraine, UNICEF is forecasting to procure 1.1 million doses of MMR vaccine on an urgent basis in addition to the 1.4 million doses forecasted for country's routine immunization in 2018. Ukraine's total forecast of 2.5 million doses for 2018 is included in the forecasted demand for MMR-2 for 2018.

For the urgent requirement of 1.1 million doses, UNICEF may consider alternative offers for vaccine for example with reduced shelf life, without VVM etc. to ensure earliest availability.

2.3.3. Estimated timing of MR catch up campaigns and Measles and MR follow up Campaigns

Historically, the demand for supplementary immunization activities has fluctuated, as different countries implement preventive campaigns at different intervals targeting varying age groups within their population.

At the same time, it has proven difficult to accurately forecast the timing of individual campaign activities. The uncertainty around the timing is connected to countries' preparedness and funding availability to conduct follow up campaigns, and their programmatic readiness to introduce MR vaccine. While extensive consultation on timing of supplementary activities has been made to provide the best estimate, the forecast remains uncertain and subject to refinement on a regular basis. As a result of this uncertainty, UNICEF expects a degree of variability in the forecast.

Below tables provide overview of supplementary activities based on our best estimate as of this time:

MR Campaigns					
2018		2019		2020	
Catch up	Follow up	Catch up	Follow up	Catch up	Follow up
Benin	Bangladesh	Comoros	Haiti	DR Congo	Angola
Congo Brazzaville	Burkina Faso	Korea DPR	Kenya	Ethiopia	Cote d'Ivoire
Eritrea	Cabo Verde	Madagascar	Myanmar		Gambia
India*	Cameroon	Niger	Papua New Guinea		Namibia
Mauritania	Ghana	Sierra Leone	Tanzania		Sao Tome & Principe
Mozambique	Timor-Leste		Zimbabwe		Zambia
Togo	Yemen				
Uganda					
*Continuation					

Measles Follow up Campaigns 2018-2020		
2018	2019	2020
Afghanistan	Djibouti	Central African Rep.
Central African Rep.	Guinea-Conakry	Equatorial Guinea
Chad	Mali	Gabon
Equatorial Guinea	Somalia	Nigeria
Guinea-Bissau	South Sudan	
Liberia		
Nigeria		
Pakistan		
Sudan		

2.4 TENDER DURATION

The tender period will be from the 1st January 2018 to the 31st December 2020.

2.5 MINIMUM QUANTITY GUARANTEES AND FIRM CONTRACTING

Subject to funding availability, UNICEF may consider innovative approaches to contracting, such as volume-based firm commitments, as part of the bidders' proposal to ensure the lowest possible price and guaranteed supply of vaccines. UNICEF seeks to mitigate manufacturer risk and uncertainty by providing the opportunity to present a comprehensive proposal through the RFP process. Such approaches may be explored by

all potential suppliers by including submission of firm commitment requests as a part of the proposal submitted in response to this RFP.

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 the vaccines listed above, as required from time to time during the term of the LTA. It will be a provision of such Arrangements, 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 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 2018-2020.

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))
- 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.
- An additional blank ALTERNATIVE PROPOSAL SHEET is available for manufacturers who wish to present alternative offer(s).

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 The Proposer may submit their proposal via email, OR in a sealed, marked envelope. Proposals received without the RFP number will be invalidated regardless of the manner of submission.

3.4.2 SEALED PROPOSAL must be securely closed in a suitable envelope, clearly MARKED on the outside with the PROPOSAL NUMBER, and despatched to arrive at UNICEF Supply Division **no later than the specified date and time on the cover page of this proposal.**

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

3.4.3 EMAILED PROPOSALS should be sent to: **supplybid@unicef.org not later than the specified date and time on the cover page of this proposal.** Proposals sent to any other email or sent after the deadline, will be invalidated.

3.4.4 EMAILED PROPOSALS instructions:

3.4.4.1 All e-mail communication in relation to the Proposal must clearly indicate the reference Bid number followed by the company name (e.g. Company Name x Ltd for DAN-2017- 502616) in the “Subject” line of the e-mail.

3.4.4.2 The Bid Form is sent as a scanned copy of an original signed form in PDF format.

3.4.4.3 Ensure the "acknowledge receipt" of your bid is received after the e-mail submission. The subject line of an "acknowledge receipt" will show "UNICEF Supply Division - Bid confirmation. Ref: "Name of Company X".

3.4.4.4 Attachments must be maximum ten (10) megabytes per email and submitted in PDF format. Larger attachments and attachments other than PDF format will not be accepted.

3.4.4.5 No other recipient should be "cc" or "bcc" in the email submission.

3.5 TIME FOR RECEIVING PROPOSALS

3.5.1 The Officer of the Bid Section will open/print 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 as instructed in 3.4.

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 Officer, Ms. Michaela Briedova (email: mbriedova@unicef.org), with copy to the Procurement Assistants, Ms. Paula Hickey (email: phickey@unicef.org) and Ms. Soraia Mendes (email: smendes@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 via posting on UNICEF's website at https://www.unicef.org/supply/index_25947.html. 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 via EMAIL or POST MAIL 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 through a written or email request (supplybid@unicef.org), sent to the BID SECTION 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.

3.11 VALIDITY OF PROPOSALS

Proposals should be valid for a period through **31 December 2020**. 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, RFP-DAN-2017-502616, Terms and Conditions referred to in Section 4.7.8, 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. This information will be used by UNICEF for evaluation and approval purposes before making an award.

3.15 RIGHTS OF UNICEF

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

3.15.2 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.

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

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

3.16 CATALOGUES

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

3.17 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

3.18 AWARD NOTIFICATION

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

3.19 PUBLIC POSTING, DISCLOSURE OF PRICES AND QUANTITIES

UNICEF reserves the right to disclose price and quantity information relevant to awards/Purchase Orders resulting from this RFP.

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

Annual awarded Weighted Average Prices (WAPs) for each vaccine presentation may be posted on the UNICEF web-site.

UNICEF reserves the right to disclose information regarding the proposals received against this RFP with the Gavi Secretariat.

3.20 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 Ø
Denmark
Attention: Vaccine Centre, Contracts Officer, Michaela Briedova

3.21 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.

3.22 DEBRIEFINGS

All Proposers receiving an award will be invited to a 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.

4. TERMS AND CONDITIONS

4.1 FORECASTED VACCINE REQUIREMENTS

Below is an overall estimated levelled out MCV demand through UNICEF for 2018-2020:

Forecasted demand for MCV for 2018-2020, in millions of doses				TOTAL
Vaccine	2018	2019	2020	
Measles-10	135	105	70	310
Measles-5	5	5	5	15
MR-10 (incl. India)	231.5	130	180	541.5
MR-5	10	15	20	45
MMR-1	1	1	1	3
MMR-2	3.5	2.5	2.5	8.5
MMR-5	8	8	8	24
MMR-10	8	8	8	24
Total forecasted demand	402	274.5	294.5	971

Please use the QUANTITATIVE PROPOSAL SHEET(s) to provide the quantities offered by year. Please also refer to Section 2 ("Background") for further information on required supply.

4.2 MANDATORY TECHNICAL REQUIREMENTS

4.2.1 WHO PREQUALIFICATION

Only vaccines which are pre-qualified by WHO will be procured by UNICEF.

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.

(a) Good Manufacturing Practices for Biological Products (WHO Technical Report Series No. 999, Annex 2, 2016)
(b) Guideline for National Authorities on Quality Assurance for Biological Products (WHO Technical Report Series No. 822, 1992)
(c) Good Manufacturing Practices for Pharmaceutical Manufacturers (WHO Technical Report Series No. 823, 1992)
(d) Good Manufacturing Practices: Requirements for sampling of starting materials (WHO Technical Report Series No. 929, 2005. Annex 2)
(e) Good Manufacturing Practices. Water for pharmaceutical use (WHO Technical Report Series No. 970, annex 2 (2012)
(f) Good Manufacturing Practices for pharmaceutical products: main principles (WHO_TRS_986_annex 2 GMP main principles)
(g) Basic elements of Good Manufacturing Practices in Pharmaceutical Production (WHO Technical Report Series No.902, 2002. Annex 5)

(h) Good manufacturing practices for sterile pharmaceutical products (WHO Technical Report Series No.961, 2011. Annex 6);
(i) Guide for Inspection of Manufacturers of Biological Products (WHO/VSQ/97.03)
(j) Regulation and Licensing of Biological Products in Countries with Newly Developing Regulatory Authorities (WHO Technical Report Series No. 858, 1995)
(k) Guidelines for National Authorities on Quality Assurance for Biological Products (WHO Technical Report Series No. No 822, 1992)
(l) General Requirements for the Sterility of Biological Substances (WHO Technical Report Series No. 530. 1973), Amendment 1995 (WHO Technical Report Series No. 872, 1998)
(m) Requirements for the Use of Animal Cells as In Vitro Substrates for the Production of Biologicals (WHO Technical Report Series No. 878, 1998)
(n) Report of a WHO Consultation on Medicinal and other Products in relation to Human and Animal Transmissible Spongiform Encephalopathies (WHO/BLG/97.2)
(o) Recommendations on Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products (WHO Technical Report Series No. 908, 2003)
(p) Guidelines on Regulatory Expectations related to the Elimination, Reduction or Replacement of Thimerosal in Vaccines (WHO Technical Report Series No. 926, 2004)
(q) Guidelines on stability evaluation of vaccines (WHO/BS/06.2049 2006)
(r) Guidelines on Clinical Evaluation of Vaccines: Regulatory Expectations (WHO Technical Report Series No. TRS 924, 2004)
(s) 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:

- Requirements for Measles, Mumps and Rubella vaccines and combined vaccines, freeze dried (Live) (WHO Technical Report Series No. 840, 1994) (WHO Technical Report Series No. 848, 1994).

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 (NRA) should be notified to WHO/Department of Essential Medicines and Health Products Department/ Prequalification (WHO/EMP/PQT) in accordance with WHO agreed timeframe. If manufacturing country regulations do not require approval of the changes by the NRA, then WHO/PQT 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 COUNTRY OF ORIGIN AND VACCINE SOURCE

Proposers shall advise country of origin of products offered (QUANTITATIVE RESPONSE SHEET). Proposers may furthermore be required to submit a Certificate of Origin of Goods

issued by the Chamber of Commerce or other equivalent authority. In addition, all Proposers not producing the vaccine offered or their own vaccine bulk concentrate must indicate the source(s) of 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 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.

4.2.6.1 NATIONAL REGULATORY LICENSURE REQUIREMENTS BY THE IMPORTING GOVERNMENTS

Proposers are expected to undertake all reasonable efforts to ensure products are registered in the countries that require registration prior to use and to keep UNICEF and WHO informed of the progress and development of same.

In the QUALITATIVE PROPOSAL SHEET (Section 5), Proposers are requested to provide information on planned, pending, and existing registrations, including expiry dates and intent to maintain such registrations.

Upon completion of the tender and successful awards, it will be a provision of the resulting LTA(s) that Proposers shall undertake the obligation to continuously update UNICEF of any new registrations in countries as well as expiry of any registration and intent to extend.

4.2.7 LABELS AND PACKAGE INSERTS

The labels on vaccine primary containers will be those 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 those agreed by WHO during prequalification 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 fulfills WHO requirements for….. (Name of vaccine)”.

Inserts shall not contradict WHO policies as indicated in the WHO Model Insert for the vaccine. Any additional information provided by the manufacturer must not confuse or contradict WHO policy on the use of that vaccine. More information about model inserts is available under the below link:
http://www.who.int/immunization_standards/vaccine_quality/model_inserts/en/

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. Any change should be approved by the NRA of Record and WHO/PQT.

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).

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, as per the terms contained in "Delivery not Acceptance: Consequences of Delayed Delivery and Non-Conforming Goods" under the UNICEF General Terms and Conditions (GTC) which are annexed to and constitute an integral part of the present RFP and any resulting LTA(s) and PO(s).

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. The numbers of samples to be retained are specified below:

Vaccines	Number of vials of finished product to be retained by the supplier for each batch (and appropriate diluent when needed)
Measles	30 vials with corresponding quantity of diluents
MR	30 vials with corresponding quantity of diluents
MMR	30 vials (multi dose) with corresponding quantity of diluents and 60 vials (single dose) with corresponding quantity of diluents

These samples shall be provided, upon request, to WHO/PQT for testing.

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 its 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

Packing/Shipping arrangements shall be in accordance with "Guidelines on the International Packaging and Shipping of Vaccines", (WHO/IVB/05.23) of the World Health Organization which can be found,
http://apps.who.int/iris/bitstream/10665/69368/1/WHO_IVB_05.23_eng.pdf or any subsequent revisions.

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''. The revision is being conducted by

WHO in consultation with industry. Any changes in requirements in the Guidelines will be implemented within a reasonable timeline.

The cost of such packaging, packing, and all temperature monitoring devices must be included in the offered price.

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 STANDARD DOCUMENTS

The Supplier shall submit to the UNICEF freight forwarder the following documentation:
a) Invoice;
b) Packing list; the Packing List must clearly indicate the Purchase Order item number(s) contained in each package, a description of the Goods, their value, quantity, gross weight, volume in cubic meters, dimensions and markings, expiry date of vaccine, and appropriate storage temperature;
c) Release certificate issued by the National Regulatory Authority of the country of manufacture for each lot of vaccine supplied;
d) If applicable, hazardous Goods documents, such as in the case of use of dry ice;
e) Any other documents as specified in each Purchase Order.

4.3.3 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.

4.3.4 LABELING AND BAR CODING

Labelling and bar coding are included in WHO's guideline "Assessing the programmatic suitability of vaccines considered for WHO prequalification" as preferred vaccine characteristics.

Programmatic preference for Labels and Barcodes are:
Labelling: Primary and secondary containers should be labelled according to the principles set out in TRS 996, Annex 2.
Bar Coding: Bar codes are recommended on all packaging levels used by manufacturers, with the exception of primary packaging, and should conform to GS1 standards. The bar codes should include Global Trade Item Number (GTIN), lot number and expiry date.

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

All shipments of vaccines on behalf of UNICEF will be arranged through UNICEF designated freight forwarders, unless otherwise specified. The awarded Proposer 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.

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: http://www.who.int/immunization_standards/vaccine_quality/pqs_e6_temp_monitoring/en/

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.

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.

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 for orders aimed at routine immunization programmes or preventive vaccination campaigns.

4.4.5 OUTBREAK RESPONSE DELIVERY LEAD TIMES

For outbreak response deliveries, suppliers are requested to have 1 million doses of Measles vaccine and 500,000 doses of MR vaccine available for shipment within 72 hours of receipt of a UNICEF Purchase Order. Suppliers will be requested to store vaccines for outbreak response and ensure that the stock is rotated to minimize reduction of vaccine shelf life.

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:

Measles, MR and MMR Vaccines: 18 months.

4.6 ADVERSE EVENTS AND RECALLS

In the execution of LTA(s) and purchase orders resulting from this RFP, the corresponding supplier shall in case of:

4.6.1 Adverse Events

The Supplier shall comply with all applicable laws, regulations and requirements. This includes monitoring, reporting and any consequent modification of product information regarding vaccine safety required under national laws and regulations in the country of manufacture, in any other country in which the vaccine receives marketing authorisation and also as required to fulfil the conditions of WHO prequalification. 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 Clinical Safety Data Management: Definitions and Standards for Expedited Reporting and the WHO Global Manual on Surveillance of Adverse Events Following Immunization.

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

4.6.2 Quality complaints and recalls

The Supplier shall notify UNICEF of any quality complaints that it becomes aware of related to the vaccine delivered to UNICEF. If any circumstance or event may require or make reasonably appropriate any recall or withdrawal of the vaccine or any field alert regarding the vaccine, the supplier shall immediately notify WHO/EMP and UNICEF and other appropriate entities. When a recall, withdrawal or field alert is required or appropriate, the supplier shall take all appropriate actions and shall bear all associated expenses.

4.7 FINANCIAL AND COMMERCIAL REQUIREMENTS

4.7.1 SUPPLIER'S REPRESENTATION

The Proposer represents and warrants that it has the personnel, experience, qualifications, facilities and all other skills and resources necessary to perform its obligations under any Agreement resulting from this RFP.

4.7.2 ACCOUNT MANAGEMENT

The Proposer shall provide UNICEF with organizational charts and names of the responsible persons within each of the following departments: 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.

UNICEF expects the primary contact person(s) to be able to execute the appropriate account management which includes: accurate and reliable planning and forecasting, efficient order processing, accurate and complete documentation, close production follow up, facilitate timely submission to NRA for release and follow-up of the same, shipping and logistics as well as any other related issues including fast response time to inquiries. Communication and documentation are expected to be in English. The communication is seen as an important prerequisite for successful account management and needs to be frequent, timely and accurate.

Suppliers are not expected to have direct contact with recipient country Governments.

4.7.3 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.

4.7.4 SUPPLIER PERFORMANCE

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.

As part of UNICEF's continuous strive to improve our ability to provide products of the appropriate standards to UNICEF programs and partners and in a timely manner, monitoring of suppliers' performance will continue to be strengthened. UNICEF has identified generic criteria that will be applied for evaluating and monitoring supplier performance against their contractual obligations as an outcome of this procurement process.

Key Categories	Performance Metrics	Performance Baseline
Time	Timeliness of Purchase Order Acknowledgement	Less than or equal to 7 working days after Purchase Order placement
	Timeliness of Notification of Goods Readiness	Notification of Goods' Readiness parameter (Greater than or equal to 3 working days before potential delivery)
	Timeliness of Delivery	Less than or equal to 5 working days after Purchase Order delivery date

4.7.5 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.

4.7.6 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.

4.7.7 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.

4.7.8 CURRENCY OF PROPOSAL

The currency of the proposal shall be either 1) US Dollars or 2) US Dollars and EURO.

Proposers wishing to offer in EURO are requested to offer one price in US Dollars and one price in EURO, leaving it to UNICEF's sole discretion to determine which price to accept and consider for award. For evaluation purposes, the EURO price will be converted to US Dollars using the official UN currency exchange rate on the deadline date for receipt of proposals.

4.7.9 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.

4.7.10 INCOTERMS AND UNIT PRICING

Unit pricing for vaccines covered by this solicitation 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.

Unit pricing for MR vaccine supply for the introduction campaigns in India is to be provided on DAP Indian Consignees basis (INCOTERMS 2010). The specific delivery addresses will be indicated at the time of Purchase Order issuance.

4.7.11 VVM and UNIT PRICING
UNICEF requests vaccines with VVM. Unit pricing is to include the price of VVM.

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 MINIMUM QUANTITY GUARANTEES AND FIRM CONTRACTING
UNICEF accepts alternative proposals conditional upon firm UNICEF commitment to purchase 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 or guarantees.

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.

Alternative proposals should come together with proposals adhering to UNICEF standard contracting conditions.

4.7.14 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.

4.8 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.

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.

The below table lists the qualitative and quantitative evaluation criteria for the proposal evaluation that determines the basis for award:

Procurement Objective: Vaccine Security Objective: Uninterrupted supply for all countries procuring through UNICEF to meet the demand for their routine needs as well as supplementary requirements for campaigns; MR introduction through catch up campaigns, Measles or MR follow up campaigns, as well as immediate availability to react to outbreaks by ensuring rolling buffer stock availability.	
Quantitative Criteria	**Qualitative Criteria**
Product presentation offered	WHO pre-qualified vaccine
Quantity offered	Experience in vaccine supply and delivery: Number of years of production and delivery (quantity); Customer reference list (applicable to all suppliers with less than 3 years' experience as a UNICEF supplier supplying against long-term agreement) Number and names of regulatory bodies where products are registered and expiry of the registration, including intent to maintain such registrations upon expiry, as well as names of regulatory bodies where registration is ongoing/pending with date of submission of documentation for registration Proven reliable and firm forecasted supply Realistic lead-time offered
Validity of offer (1 Jan 2018 – 31 Dec 2020)	Access to necessary bulk production capacity, and sharing of documentation if bulk supply is contracted
Lead-time for quantities within forecast	Ability to provide accurate and reliable planning and forecasting, including monitoring NRA release, efficient order processing, accurate and complete documentation, close production follow-up
Product shelf life and shelf life at time of delivery	Medium and long term plans for production of the vaccine being offered, including overview of business factors affecting the decision to produce the vaccine at the quantities offered
Bulk production and filling capacity	Adherence to packing and shipping requirements, including temperature monitoring devices
Total finish product capacity	Support to timely AEFI reporting
Product mix offered	Elaboration on flexibility for supplying un-forecasted quantities (timing, quantities)
Total quantities supplied to other customers	Initiative to resolve problems in a satisfactory and fast manner
Weight and volume	Supplier performance:

	Existing suppliers: Proven capacity to provide quantities offered, on time deliveries, reliable and firm forecasted supply, accurate monthly forecasting, realistic quantity offered; Pipeline suppliers: Establishing of milestones to WHO PQ and supply to UNICEF; dates for clinical trials yet to be completed (Phase I, II and III); dates for national licensure in country of production; date of submission to WHO PQ; expected date of WHO PQ; expected date of first supply to UNICEF. Further information as per section 4.8.4.
VVM included	Account management resources (organizational charts with names) and customer service capabilities
Warehouse capacity for finished and bulk, maximum storage in number of doses and any time	Willingness to include a Vaccine Arrival Report as part of shipping documents
Cold chain requirement	Possible effects of quantities offered on other vaccine presentations
UNGM registration	Agreement to store vaccines on an urgent need basis as well as under what circumstances (ability to keep buffer stock)
	Agreement to outbreak response conditions for a specific quantity with ability to supply the vaccine within 72 hours from UNICEF order receipt.
	MMR Vaccine with Jeryl Lynn mumps strain required for Ukraine (Please refer to QUANTITATIVE PROPOSAL SHEET MMR-2 vaccine and section 2.3.2.2.): Availability to supply requirement of 1.1 million doses for outbreak response on an urgent basis.
Procurement Objective: Ensuring sustainable, but affordable prices	
Quantitative Criteria	**Qualitative Criteria**
Price per dose (FCA nearest int. airport for all vaccines except MR for India which should be based on DAP Indian Consignees)	Prices compared to other offers Reciprocity in any special contracting terms
Alternative offers providing additional beneficial affordability/prices/commercial terms	Factors that influence the pricing offered to UNICEF
Payment terms	

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 4.2 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 and taking into consideration the current market situation for the vaccine, quantities will be awarded to suppliers in accordance with the objectives of this solicitation. Some quantities may be left un-awarded if UNICEF believes this will help achieving the objectives of the tender.

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 EVALUATION OF PROPOSALS INCLUDING PRODUCTS NOT YET WHO PRE-QUALIFIED

For products offered that are not WHO pre-qualified, the manufacturers are requested to include in their response a detailed plan on the timeline to obtain WHO pre-qualification. The timeline will include information regarding the product and plans for manufacturing and licensing, i,e.:

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 proposal from the manufacturer is deemed of interest to UNICEF, UNICEF will advise the manufacturer accordingly and will request that UNICEF is regularly informed about the progress of the process in accordance with 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:

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); or
4) If it meets the specific objectives of the tender

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 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.

4.9.2 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.

4.9.3 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.

4.9.4 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.

4.9.5 MOST FAVOURED NATION
4.9.5.1 The Proposer confirms that the prices with respect to the goods specified in the Proposal are the most favourable prices available to any customer of the Proposer (or any of the Proposer's affiliates).

4.9.5.2 If at any time during the term of the LTA resulting from the Proposal any other customer of the Proposer (or of any of the Proposer's affiliates) obtains more favourable pricing terms than those provided to UNICEF, the Proposer will retroactively adjust the price(s) and related pricing terms under the LTA and in the relevant Purchase Order(s) to conform to the more favourable terms and the Proposer will promptly pay UNICEF any amounts owing to UNICEF as a result of such retroactive price adjustment.

4.9.6 UNICEF 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.

4.9.7 LIQUIDATED DAMAGES
Any Purchase Orders awarded in connection with this Solicitation Document will include the following clause on liquidated damages:

"In addition to, and without prejudice to any of the other rights and remedies of UNICEF including, but not limited to, those set out in the UNICEF General Terms and Conditions of Contract (Goods), if the Supplier fails to deliver the Goods under this Purchase Order in accordance with the stated time for delivery, or if UNICEF exercises its right to reject Goods that do not conform to the requirements in this Purchase Order, UNICEF may claim liquidated damages from the Supplier and, at UNICEF's option, the Supplier will pay such liquidated damages to UNICEF or UNICEF will deduct such liquidated damages from the Supplier's invoice(s). Such liquidated damages will be calculated as follows: one half of one per cent (0.5%) of the Price of such Goods for each day of delay, until delivery of conforming Goods, up to a maximum of ten per cent (10%) of the value of this Purchase Order. The payment or deduction of such liquidated damages will not relieve the Supplier from any of its other obligations or liabilities pursuant to this Purchase Order."

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 of Contracts (Goods) 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 Officer Ms. Michaela Briedova (email: mbriedova@unicef.org) with copy to the Procurement Assistants, Ms. Paula Hickey (email: phickey@unicef.org) and Ms. Soraia Mendes (email: smendes@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-2017-502616** 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:_____

TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET

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. Total annual quantities supplied to other customers.

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 planned for or pending registration, already registered as well as original date of registration, expiry date of registration as applicable and intent to maintain 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
   (1) Bulk (if bulk producer)
   (2) Final filled product for the offered vaccine
   (3) If the vaccine bulk is not produced by the Proposer, please advise 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 indicate warehouse capacity for bulk and finish product, indicating the maximum storage capacity in number of doses at any time.

9. 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.

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

11. 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.

12. For proposers offering Measles and MR Vaccine: Please explicitly confirm that your company is able to prepare an order for 1 million doses of Measles vaccine and/or 500,000 doses of MR Vaccine within 72 hours from receipt of a UNICEF purchase order without any impact on other forecasted requirements from UNICEF.

13. Please indicate the company willingness to include a Vaccine Arrival Report (VAR) as part of the shipping documents, as per section 4.4.2.

QUANTITATIVE PROPOSAL SHEET

Measles-10 vaccine

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:

Measles Vaccine, 10 dose vial/ampoule, paediatric dose, lyophilized, with diluent.

Quantities per year in vials and doses:
2018: 13,500,000 vials (135,000,000 doses)
2019: 10,500,000 vials (105,000,000 doses)
2020: 7,000,000 vials (70,000,000 doses)

Comments: The forecast represents the estimated needs for routine vaccination and supplementary immunisation activities in countries.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

Measles-5 vaccine

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:

Measles Vaccine, 5 dose vial/ampoule, paediatric dose, lyophilized, with diluent.

Quantities per year in vials and doses:
2018: 1,000,000 vials (5,000,000 doses)
2019: 1,000,000 vials (5,000,000 doses)
2020: 1,000,000 vials (5,000,000 doses)

Comments: The forecast represents the estimated needs for routine vaccination in countries.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

MR-10 vaccine

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:

Measles and Rubella (MR) vaccine, 10 dose vial, paediatric dose, lyophilized, with diluent

Quantities per year in vials and doses:
2018: 12,000,000 vials (120,000,000 doses)
2019: 13,000,000 vials (130,000,000 doses)
2020: 18,000,000 vials (180,00,000 doses)

Comment: The forecast represents the estimated needs for routine vaccination and supplementary immunisation activities in countries.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

MR-10 vaccine for Indian Consignees

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:

Measles and Rubella (MR) vaccine, 10 dose vial, paediatric dose, lyophilized, with diluent.

Quantities per year in vials and doses:
2018: 11,150,000 vials (111,500,000 doses)

Comment: This represents the remaining forecast for GAVI funded MR vaccine for the MR introduction campaign in **India**.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial DAP Indian Consignees USD*	Unit Price per vial DAP Indian Consignees EURO*	Conditions/ Discounts*	Total Amount (USD)
2018						

* 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 Sections 3.12, and 4.7.8 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.

INCOTERMS (2010) DAP all India: _____

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine's shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

MR-5 vaccine

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:

Measles and Rubella (MR) vaccine, 5 dose vial, paediatric dose, lyophilized, with diluent.

Quantities per year in vials and doses:
2018: 2,000,000 vials (10,000,000 doses)
2019: 3,000,000 vials (15,000,000 doses)
2020: 4,000,000 vials (20,000,000 doses)

Comment: The forecast represents the estimated needs for routine vaccination in countries.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

MMR-1 vaccine

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:

Measles, Mumps and Rubella (MMR) vaccine, 1 dose vial, paediatric dose, lyophilized, with diluent

Quantities per year in vials and doses:
2018: 1,000,000 vials (1,000,000 doses)
2019: 1,000,000 vials (1,000,000 doses)
2020: 1,000,000 vials (1,000,000 doses)

Comment: The forecast represents the estimated needs for routine vaccination in countries.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

MMR-2 vaccine

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:

Measles, Mumps and Rubella (MMR) vaccine, 2 dose vial, paediatric dose, lyophilized, with diluent **Jeryl Lynn** mumps strain

Quantities per year in vials and doses:
2018: 1,750,000 vials (3,500,000 doses)
2019: 1,250,000 vials (2,500,000 doses)
2020: 1,250,000 vials (2,500,000 doses)

Comment: The forecast represents the estimated needs for routine vaccination in countries.

The demand may be satisfied through supply in any presentation.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

MMR-5 vaccine

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:

Measles, Mumps and Rubella (MMR) vaccine, 5 dose vial, paediatric dose, lyophilized, with diluent

Quantities per year in vials and doses:
2018: 1,600,000 vials (8,000,000 doses)
2019: 1,600,000 vials (8,000,000 doses)
2020: 1,600,000 vials (8,000,000 doses)

Comment: The forecast represents the estimated needs for routine vaccination in countries.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

QUANTITATIVE PROPOSAL SHEET

MMR-10 vaccine

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:

Measles, Mumps and Rubella (MMR) vaccine, 10 dose vial, paediatric dose, lyophilized, with diluent

Quantities per year in vials and doses:
2018: 800,000 vials (8,000,000 doses)
2019: 800,000 vials (8,000,000 doses)
2020: 800,000 vials (8,000,000 doses)

Comment: The forecast represents the estimated needs for routine vaccination in countries.

Period	Quantity of doses offered	Quantity of vials offered	Unit Price per vial FCA Int'l airport USD*	Unit Price per vial FCA Int'l airport EURO*	Conditions/ Discounts**	Total Amount (USD)
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

ALTERNATIVE PROPOSAL SHEET

Manufacturers can provide alternative proposals using this offer 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:

Vaccine: **Description:** **Vial Size:**						
Period	**Quantity of doses offered**	**Quantity of vials offered**	**Unit Price per vial FCA Int'l airport USD***	**Unit Price per vial FCA Int'l airport EURO***	**Conditions/ Discounts****	**Total Amount (USD)**
2018						
2019						
2020						

* 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 Sections 3.12, and 4.7.8 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.

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

Vaccine Vial Monitors: Yes: _____ No: _____

Total annual production capacity: _____

Vaccine shelf life at time of shipment: _____

Vaccination schedule: _____

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

Country of Origin: _____

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

Additional comments:

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:

	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:		

E. 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:		

MONTHLY OFFERED QUANTITIES (DOSES)

YEAR 2018

PLEASE ENTER QUANTITIES IN DOSES

Vaccine offered: _____

Vaccine	
January 2018	
February 2018	
March 2018	
April 2018	
May 2018	
June 2018	
July 2018	
August 2018	
September 2018	
October 2018	
November 2018	
December 2018	
TOTAL 2018	

MONTHLY OFFERED QUANTITIES (DOSES)

YEAR 2019

PLEASE ENTER QUANTITIES IN DOSES

Vaccine offered: _____

Vaccine	
January 2019	
February 2019	
March 2019	
April 2019	
May 2019	
June 2019	
July 2019	
August 2019	
September 2019	
October 2019	
November 2019	
December 2019	
TOTAL 2019	

MONTHLY OFFERED QUANTITIES (DOSES)

YEAR 2020

PLEASE ENTER QUANTITIES IN DOSES

Vaccine offered: _____

Vaccine	
January 2020	
February 2020	
March 2020	
April 2020	
May 2020	
June 2020	
July 2020	
August 2020	
September 2020	
October 2020	
November 2020	
December 2020	
TOTAL 2020	

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):

Annex A – GENERAL TERMS AND CONDITIONS OF CONTRACT

ANNEX A

GENERAL TERMS AND CONDITIONS OF CONTRACT (Goods)

1. DEFINITIONS AND UNICEF SUPPLY WEBSITE

1.1 In these General Terms and Conditions (Goods), the following terms have the following meaning:

(a) "Affiliates" means, with respect to the Supplier, any of its corporate affiliates or associates, including parent entities, subsidiaries, and other entities in which it owns a substantial interest.

(b) "Confidential Information" means information or data that is designated as confidential at the time of exchange between the Parties or promptly identified as confidential in writing when furnished in intangible form or disclosed orally, and includes information, the confidential or proprietary nature of which is or should be reasonably apparent from the inherent nature, quality or characteristics of such information.

(c) "Consignee" means the consignee designated in the Contract.

(d) "Contract" means the purchase contract that incorporates these General Terms and Conditions (Goods). It includes purchase orders issued by UNICEF, whether or not they are issued under a long-term arrangement or similar contract.

(e) "Goods" means the goods specified in the relevant section of the Contract.

(f) "Host Government" means a Government with which UNICEF has a programme of development cooperation, and includes a Government of a country in which UNICEF provides humanitarian assistance.

(g) "INCOTERMS" means the international commercial terms known as the INCOTERMS® rules, issued by the International Chamber of Commerce, most-recently issued at the effective date of the Contract. References in the Contract to trade terms (such as "FCA", "DAP" and "CIP") are references to those terms as defined by the INCOTERMS.

(h) "Parties" means the Contractor and UNICEF together and a "Party" means each of the Contractor and UNICEF.

(i) Supplier's "Personnel" means the Supplier's officials, employees, agents, individual sub-contractors and other representatives.

(j) "Price" is defined in Article 3.1.

(k) "Supplier" is the supplier named in the Contract.

(l) "UNICEF Supply Website" means UNICEF's public access webpage available at http://www.unicef.org/supply/index_procurement_policies.html, as may be updated from time to time.

1.2 These General Terms and Conditions of Contract, UNICEF's Policy Prohibiting and Combatting Fraud and Corruption, the UNICEF's Policy on Conduct Promoting the Protection and Safeguarding of Children, the UN Supplier Code of Conduct, and UNICEF's Information Disclosure Policy referred to in the Contract, as well as other policies applicable to the Supplier, are publicly available on the UNICEF Supply Website. The Supplier represents that it has reviewed all such policies as of the effective date of the Contract.

2. DELIVERY; INSPECTION; RISK OF LOSS

2.1 The Supplier will deliver the Goods to the Consignee at the place and within the time period for delivery stated in the Contract. The Supplier will comply with the INCOTERM or similar trade term expressly stated in the Contract as applying to the Goods to be supplied under the Contract and all other delivery terms and instructions stated in the Contract. Notwithstanding any INCOTERM, the Supplier will obtain any export licences required for the Goods. The Supplier will ensure that UNICEF receives all necessary transport documents in a timely manner so as to enable UNICEF to take delivery of the Goods in accordance with the requirements of the Contract. The Supplier will neither seek nor accept instructions from any entity other than UNICEF (or entities authorized by UNICEF to give instructions to the Supplier) in connection with the supply and delivery of the Goods.

2.2 The Supplier will use its best efforts to accommodate reasonable requests for changes (if any) to the requirements for the Goods (such as packaging, packing and labeling requirements), shipping instructions or delivery date of the Goods set out in the Contract. If UNICEF requests any material change to the requirements for the Goods, shipping instructions or delivery date, UNICEF and the Supplier will negotiate any necessary changes to the Contract, including as to Price and the time schedule. Any such agreed changes will become effective only when they are set out in a written amendment to the Contract signed by both UNICEF and the Supplier. Should the Parties fail to agree on any such changes within thirty (30) days, UNICEF will have the option to terminate the Contract without penalty notwithstanding any other provision of the Contract.

2.3 The Supplier acknowledges that UNICEF may monitor the Supplier's performance under the Contract. The Supplier agrees to provide its full cooperation with such performance monitoring, at no additional cost or expense to UNICEF, and provide relevant information as reasonably requested by UNICEF, including, but not limited to, the date of receipt of the Contract, detailed delivery status, costs to be charged and payments made by UNICEF or pending.

Inspection

2.4 UNICEF or the Consignee (if different from UNICEF) will have a reasonable time to inspect the Goods after delivery. At UNICEF's request, the Supplier will provide its reasonable cooperation to UNICEF or the Consignee with regard to such inspection, including but not limited to access to production data, at no charge. The Supplier acknowledges that any inspection of the Goods by or on behalf of UNICEF or the Consignee does not constitute a determination that the specifications for the Goods set out in the Contract (including the mandatory technical requirements) have or have not been met. The Supplier will be required to comply with its warranty and other contractual obligations whether or not UNICEF or the Consignee carries out an inspection of the Goods.

Delivery not Acceptance; Consequences of Delayed Delivery and Non-conforming Goods

2.5 If the Supplier determines it will be unable to deliver all or some of the Goods to the Consignee by the delivery date(s) stipulated in the Contract, the Supplier will (a) immediately consult with UNICEF to determine the most expeditious means for delivering the Goods; and (b) use an expedited means of delivery, at the Supplier's cost (unless the delay is due to force majeure as defined in Article 6.7 below), if reasonably requested by UNICEF to do so. Partial deliveries of Goods will not be accepted unless prior written approval for such partial delivery has been given by UNICEF to the Supplier.

2.6 Delivery of the Goods will not constitute acceptance of the Goods. If some or all of the Goods do not conform to the requirements of the Contract or if the Supplier delivers the Goods late or fails to deliver the Goods (or any part of the Goods) in accordance with the agreed delivery dates and delivery terms and instructions, UNICEF may, without prejudice to any of its other rights and remedies, exercise one or more of the following rights under the Contract at UNICEF's option:

(a) UNICEF can reject and refuse to accept any or all of the Goods (including those that do conform to the Contract). If UNICEF rejects the Goods, the Supplier will, at its own cost, arrange for the prompt return of the rejected Goods and, at UNICEF's option, the Supplier will promptly replace the rejected Goods with Goods of equal or better quality (and will be responsible for all costs related to such replacement) or UNICEF may exercise its other rights set out below;

(b) UNICEF may procure all or part of the Goods from other sources, in which case the Supplier will be responsible for any additional costs beyond the balance of the Price for such Goods;

(c) Upon UNICEF's demand, the Supplier will refund all payments (if any) made by UNICEF in respect of the rejected Goods or the Goods that have not been delivered in accordance with the delivery dates and delivery terms;

(d) UNICEF can give written notice of breach and, if the Supplier fails to remedy the breach, can terminate the Contract in accordance with Article 6.1 below;

(e) UNICEF can require the Supplier to pay liquidated damages as set out in the Contract.

2.7 Further to Article 11.6 below, the Supplier expressly acknowledges that if, in respect of any consignment, UNICEF takes delivery of all or some of the Goods that have been delivered late or otherwise not in full compliance with the delivery terms and instructions or that are not in full conformity with the requirements of the Contract, this does not constitute a waiver of UNICEF's rights in respect of such late delivery or non-compliant Goods.

Risk of Loss; Title to Goods

2.8 Risk of loss, damage to or destruction of Goods supplied under the Contract, and responsibility for arranging and paying for freight and insurance, will be governed by the INCOTERM or similar trade term expressly stated in the Contract as applying to the Goods supplied under the Contract and any other express terms of the Contract. In the absence of any such INCOTERM or similar trade term or other express terms, the following provisions will apply: (a) the entire risk of loss, damage to or destruction of the Goods will be borne exclusively by the Supplier until physical delivery of the Goods to

the Consignee has been completed in accordance with the Contract; and (b) the Supplier will be solely liable for making all transport arrangements and for payment of freight and insurance costs for the shipment and delivery of the Goods in accordance with the requirements of the Contract.

2.9 Unless otherwise expressly provided in the Contract, title in and to the Goods will pass from the Supplier to the Consignee upon delivery of the Goods in accordance with the applicable delivery terms and acceptance of the Goods in accordance with the Contract.

3. PRICE; INVOICING; TAX EXEMPTION; PAYMENT TERMS

3.1 The price for the Goods is the amount specified in the price section of the Contract (the "Price"), it being understood that such amount is specified in United States dollars unless otherwise expressly provided for in the price section of the Contract. The Price includes the cost of packaging and packing the Goods in accordance with the requirements of the Contract and delivery in accordance with the applicable delivery terms. The Price is inclusive of all costs, expenses, charges or fees that the Supplier may incur in connection with the performance of its obligations under the Contract; provided that, without prejudice to or limiting the provisions of Article 3.3 below, all duties and other taxes imposed by any authority or entity must be separately identified. It is understood and agreed that the Supplier will not request any change to the Price after delivery of the Goods by the Supplier and that the Price cannot be changed except by written agreement between the Parties before the Goods are delivered.

3.2 The Supplier will issue invoices to UNICEF only after the Supplier has fulfilled the delivery terms of the Contract. The Supplier will issue (a) one (1) invoice in respect of the payment being sought, in the currency specified in the Contract and in English, indicating the Contract identification number listed on the front page of the Contract; and (b) copies of the shipping documents and other supporting documents as specified in the Contract.

3.3 The Supplier authorizes UNICEF to deduct from the Supplier's invoices any amount representing direct taxes (except charges for utilities services) and customs restrictions, duties and charges of a similar nature in respect of articles imported or exported for UNICEF's official use, in accordance with the exemption from tax in Article II, Section 7 of the Convention of the Privileges and Immunities of the United Nations, 1946. In the event any governmental authority refuses to recognize this exemption from taxes, restrictions, duties or charges, the Supplier will immediately consult with UNICEF to determine a mutually acceptable procedure. The Supplier will provide full cooperation to UNICEF with regard to securing UNICEF's exemption from, or refund of amounts paid as, value-added taxes or taxes of a similar nature.

3.4 UNICEF will notify the Supplier of any dispute or discrepancy in the content or form of any invoice. With respect to disputes regarding only a portion of such invoice, UNICEF will pay the Supplier the amount of the undisputed portion in accordance with Article 3.5 below. UNICEF and the Supplier will consult in good faith to promptly resolve any dispute with respect to any invoice. Upon resolution of such dispute, any amounts that have not been charged in accordance with the Contract will be deducted from the invoice(s) in which they appear and UNICEF will pay any agreed remaining items in the invoice(s) in accordance with Article 3.5 within thirty (30) days after the final resolution of such dispute.

3.5 UNICEF will pay the uncontested amount of the Supplier's invoice within thirty (30) days of receiving both the invoice and the shipping documents and other supporting documents, as referred to in Article 3.2 above. The amount paid will reflect any discount(s) shown under the payment terms of the Contract. The Supplier will not be entitled to interest on any late payment or any sums payable under the

Contract nor any accrued interest on payments withheld by UNICEF in connection with a dispute. Payment will not relieve the Supplier of its obligations under the Contract. Payment will not be deemed acceptance of the Goods or waiver of any rights with regard to the Goods.

3.6 Each invoice will confirm the Supplier's bank account details provided to UNICEF as part of the Supplier's registration process with UNICEF. All payments due to the Supplier under the Contract will be made by electronic funds transfer to that bank account. It is the Supplier's responsibility to ensure that the bank details supplied by it to UNICEF are up-to-date and accurate and notify UNICEF in writing by an authorized representative of the Supplier of any changes in bank details together with supporting documentation satisfactory to UNICEF.

3.7 The Supplier acknowledges and agrees that UNICEF may withhold payment in respect of any invoice if, in UNICEF's opinion, the Supplier has not performed in accordance with the terms and conditions of the Contract, or if the Supplier has not provided sufficient documentation in support of the invoice.

3.8 UNICEF will have the right to set off against any amount or amounts due and payable by UNICEF to the Supplier under the Contract, any payment, indebtedness or other claim (including, without limitation, any overpayment made by UNICEF to the Supplier) owing by the Supplier to UNICEF under the Contract or under any other contract or agreement between the Parties. UNICEF will not be required to give the Supplier prior notice before exercising this right of set-off (such notice being waived by the Supplier). UNICEF will promptly notify the Supplier after it has exercised such right of set-off, explaining the reasons for such set-off, provided however that the failure to give such notification will not affect the validity of such set-off.

3.9 Each of the invoices paid by UNICEF may be subject to a post-payment audit by UNICEF's external and internal auditors or by other authorised agents of UNICEF, at any time during the term of the Contract and for three (3) years after the Contract terminates. UNICEF will be entitled to a refund from the Supplier of amounts such audit or audits determine were not in accordance with the Contract regardless of the reasons for such payments (including but not limited to the actions or inactions of UNICEF staff and other personnel).

4. REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION; INSURANCE

Representations and Warranties

4.1 The Supplier represents and warrants that as of the effective date and throughout the term of the Contract: (a) it has the full authority and power to enter into the Contract and to perform its obligations under the Contract and the Contract is a legal, valid and binding obligation, enforceable against it in accordance with its terms; (b) it has, and will maintain throughout the term of the Contract, all rights, licenses, authority and resources necessary, as applicable, to develop, source, manufacture and supply the Goods and to perform its other obligations under the Contract; (c) all of the information concerning the Goods and the Supplier that it has previously provided to UNICEF, or that it provides to UNICEF during the term of the Contract, is true, correct, accurate and not misleading; (d) it is financially solvent and is able to supply the Goods to UNICEF in accordance with the terms and conditions of the Contract; (e) the use or supply of the Goods does not and will not infringe any patent, design, trade-name or trade-mark; (f) it has not and will not enter into any agreement or arrangement that restrains or restricts any person's rights to use, sell, dispose of or otherwise deal with the Goods; and (g) the development, manufacture and supply of the Goods is, and will continue to be, in compliance with all applicable laws, rules and regulations. The Supplier will fulfill its commitments with the fullest regard to the interests of

UNICEF and will refrain from any action which may adversely affect UNICEF or the United Nations.

4.2 The Supplier further represents and warrants that the Goods (including packaging): (a) conform to the quality, quantity and specifications for the Goods stated in the Contract (including, in the case of perishable or pharmaceutical products, the shelf life specified in the Contract); (b) conform in all respects to the technical documentation provided by the Supplier in respect of such Goods and, if samples were provided to UNICEF prior to entering into the Contract, are equal and comparable in all respects to such samples; (c) are new and factory-packed; (d) are fit for the purposes for which such goods are ordinarily used and for purposes expressly made known to the Supplier by UNICEF in the Contract; (e) are of consistent quality and free from faults and defects in design, manufacture, workmanship and materials; (f) are free from all liens, encumbrances or other third party claims; and (g) are contained or packaged in accordance with the standards of export packaging for the type and quantities of the Goods specified in the Contract, and for the modes of transport of the Goods specified in the Contract (including but not limited to, in a manner adequate to protect them in such modes of transport), and marked in a proper manner in accordance with the instructions stipulated in the Contract and applicable law.

4.3 The warranties provided in Article 4.2 will remain valid for the warranty period specified in the Contract; provided that (a) the warranty period for pharmaceutical goods or other perishable products will be no less than the shelf-life of those Goods specified in the Contract; and (b) if no warranty period or shelf-life is specified in the Contract, the warranties will remain valid from the date the Supplier signs the Contract until the day twelve (12) months after fulfillment of the delivery terms or such later date as may be prescribed by law.

4.4 If the Supplier is not the original manufacturer of the Goods or any part of the Goods, the Supplier assigns to UNICEF (or, at UNICEF's instructions, the Government or other entity that receives the Goods) all manufacturers' warranties in addition to any other warranties under the Contract.

4.5 The representations and warranties made by the Supplier in Articles 4.1 and 4.2 and the Supplier's obligations in Articles 4.3 and 4.4 above are made to and are for the benefit of (a) each entity that makes a direct financial contribution to the purchase of Goods; and (b) each Government or other entity that receives the Goods.

Indemnification

4.6 The Supplier will indemnify, hold and save harmless and defend, at its own expense, UNICEF, its officials, employees, consultants and agents, each entity that makes a direct financial contribution to the purchase of the Goods and each Government or other entity that receives the Goods, from and against all suits, claims, demands, losses and liability of any nature or kind, including their costs and expenses, by a third party and arising out of the acts or omissions of the Supplier or its Personnel or sub-contractors in the performance of the Contract. This provision will extend to but not be limited to (a) claims and liability in the nature of workers' compensation; (b) product liability; and (c) any actions or claims pertaining to the alleged infringement of a patent, design, trade-name or trade-mark arising in connection with the Goods or other liability arising out of the use of patented inventions or devices, copyrighted material or other intellectual property provided or licensed to UNICEF under the Contract or used by the Supplier, its Personnel or sub-contractors in the performance of the Contract.

4.7 UNICEF will report any such suits, proceedings, claims, demands, losses or liability to the Supplier within a reasonable period of time after having received actual notice. The Supplier will have sole control of the defence, settlement and compromise of any such suit, proceeding, claim or demand except with respect to the assertion or defence of the privileges and immunities of UNICEF or any matter relating to UNICEF's privileges and immunities (including matters relating to UNICEF's relations with

Host Governments), which as between the Supplier and UNICEF, only UNICEF itself (or relevant governmental entities) will assert and maintain. UNICEF will have the right, at its own expense, to be represented in any such suit, proceeding, claim or demand by independent counsel of its own choosing.

Insurance

4.8 The Supplier will comply with the following insurance requirements:

(a) The Supplier will have and maintain in effect with reputable insurers and in sufficient amounts, insurance against all of the Supplier's risks under the Contract (including, but not limited to, the risk of claims arising out of or related to the Supplier's performance of the Contract), including the following:

(i) Insurance against all risks in respect of its property and any equipment used for the performance of the Contract;

(ii) General liability insurance against all risks in respect of the Contract and claims arising out of the Contract including, but not limited to, product liability insurance, in an adequate amount to cover all claims arising from or in connection with the Supplier's performance under the Contract. The Supplier's product liability insurance will cover the direct and indirect financial consequences of liability (including all costs, including replacement costs, related to recall campaigns) sustained by UNICEF or third parties as a result of or relating to the Goods;

(iii) All appropriate workers' compensation and employer's liability insurance, or its equivalent, with respect to its Personnel and sub-contractors to cover claims for death, bodily injury or damage to property arising from the performance of the Contract; and

(iv) Such other insurance as may be agreed upon in writing between UNICEF and the Supplier.

(b) The Supplier will maintain the insurance coverage referred to in Article 4.8(a) above during the term of the Contract and for a period after the Contract terminates extending to the end of any applicable limitations period with regard to claims against which the insurance is obtained.

(c) The Supplier will be responsible to fund all amounts within any policy deductible or retention.

(d) Except with regard to the insurance referred to in paragraph (a)(iii) above, the insurance policies for the Supplier's insurance required under this Article 4.8 will (i) name UNICEF as an additional insured; (ii) include a waiver by the insurer of any subrogation rights against UNICEF; and (iii) provide that UNICEF will receive thirty (30) days' written notice from the insurer prior to any cancellation or change of coverage.

(e) The Supplier will, upon request, provide UNICEF with satisfactory evidence of the insurance required under this Article 4.8.

(f) Compliance with the insurance requirements of the Contract will not limit the Supplier's liability either under the Contract or otherwise.

Liability

4.9 The Supplier will pay UNICEF promptly for all loss, destruction or damage to UNICEF's property caused by the Supplier's Personnel or sub-contractors in the performance of the Contract.

5. INTELLECTUAL PROPERTY AND OTHER PROPRIETARY RIGHTS; CONFIDENTIALITY

Intellectual Property and Other Proprietary Rights

5.1 Unless otherwise expressly provided for in the Contract:

(a) Subject to paragraph (b) of this Article 5.1, UNICEF will be entitled to all intellectual property and other proprietary rights with regard to products, processes, inventions, ideas, know-how, data or documents and other materials ("Contract Materials") that (i) the Supplier develops for UNICEF under the Contract and which bear a direct relation to the Contract or (ii) are produced, prepared or collected in consequence of, or during the course of, the performance of the Contract. The term "Contract Materials" includes, but is not limited to, all maps, drawings, photographs, plans, reports, recommendations, estimates, documents developed or received by, and all other data compiled by or received by, the Supplier under the Contract. The Supplier acknowledges and agrees that Contract Materials constitute works made for hire for UNICEF. Contract Materials will be treated as UNICEF's Confidential Information and will be delivered only to authorized UNICEF officials on expiry or termination of the Contract.

(b) UNICEF will not be entitled to, and will not claim any ownership interest in, any intellectual property or other proprietary rights of the Supplier that pre-existed the performance by the Supplier of its obligations under the Contract, or that the Supplier may develop or acquire, or may have developed or acquired, independently of the performance of its obligations under the Contract. The Supplier grants to UNICEF a perpetual license to use such intellectual property or other proprietary rights solely for the purposes of and in accordance with the requirements of the Contract.

(c) At UNICEF's request, the Supplier will take all necessary steps, execute all necessary documents and generally assist in securing such proprietary rights and transferring (or, in the case, intellectual property referred to in paragraph (b) above, licensing) them to UNICEF in compliance with the requirements of the applicable law and of the Contract.

Confidentiality

5.2 Confidential Information that is considered proprietary by either Party or that is delivered or disclosed by one Party ("Discloser") to the other Party ("Recipient") during the course of performance of the Contract will be held in confidence by the Recipient. The Recipient will use the same care and discretion to avoid disclosure of the Discloser's Confidential Information as the Recipient uses for its own Confidential Information and will use the Discloser's Confidential Information solely for the purpose for which it was disclosed to the Recipient. The Recipient will not disclose the Discloser's Confidential Information to any other party:

(a) except to those of its Affiliates, employees, officials, representatives, agents and sub-contractors who have a need to know such Confidential Information for purposes of performing obligations under the Contract; or

(b) unless the Confidential Information (i) is obtained by the Recipient from a third party without restriction; (ii) is disclosed by the Discloser to a third party without any obligation of confidentiality; (iii) is known by the Recipient prior to disclosure by the Discloser; or (iv) at any time is developed by the Recipient completely independently of any disclosures under the Contract.

5.3 If the Supplier receives a request for disclosure of UNICEF's Confidential Information pursuant to any judicial or law enforcement process, before any such disclosure is made the Supplier (a) will give UNICEF sufficient notice of such request in order to allow UNICEF to have a reasonable opportunity to secure the intervention of the relevant national Government to establish protective measures or take such other action as may be appropriate; and (b) will so advise the relevant authority that requested disclosure. UNICEF may disclose the Supplier's Confidential Information to the extent required pursuant to resolutions or regulations of its governing bodies.

5.4 The Supplier may not communicate at any time to any other person, Government or authority external to UNICEF, any information known to it by reason of its association with UNICEF that has not been made public, except with the prior authorization of UNICEF; nor will the Supplier at any time use such information to private advantage.

End of Contract

5.5 Upon the expiry or earlier termination of the Contract, the Supplier will:

(a) return to UNICEF all of UNICEF's Confidential Information or, at UNICEF's option, destroy all copies of such information held by the Supplier or its sub-contractors and confirm such destruction to UNICEF in writing; and

(b) will transfer to UNICEF all intellectual and other proprietary information in accordance with Article 5.1(a).

6. TERMINATION; FORCE MAJEURE

Termination by Either Party for Material Breach

6.1 If one Party is in material breach of any of its obligations under the Contract, the other Party can give it written notice that within thirty (30) days of receiving such notice the breach must be remedied (if such breach is capable of remedy). If the breaching Party does not remedy the breach within the thirty (30) days' period or if the breach is not capable of remedy, the non-breaching Party can terminate the Contract. The termination will be effective thirty (30) days after the non-breaching Party gives the breaching Party written notice of termination. The initiation of conciliation or arbitral proceedings in accordance with Article 9 (Privileges and Immunities; Settlement of Disputes) below will not be grounds for termination of the Contract.

Additional Termination Rights of UNICEF

6.2 In addition to the termination rights under Article 6.1 above, UNICEF can terminate the Contract with immediate effect upon delivery of a written notice of termination, without any liability for termination charges or any other liability of any kind:

(a) in the circumstances described in, and in accordance with, Article 7 (*Ethical*

Standards); or

(b) if the Supplier breaches any of the provisions of Articles 5.2-5.4 (*Confidentiality*); or

(c) if the Supplier (i) is adjudged bankrupt, or is liquidated, or becomes insolvent, or applies for a moratorium or stay on any payment or repayment obligations, or applies to be declared insolvent; (ii) is granted a moratorium or a stay, or is declared insolvent; (iii) makes an assignment for the benefit of one or more of its creditors; (iv) has a receiver appointed on account of the insolvency of the Supplier; (v) offers a settlement in lieu of bankruptcy or receivership; or (vi) has become, in UNICEF's reasonable judgment, subject to a materially adverse change in its financial condition that threatens to substantially affect the ability of the Supplier to perform any of its obligations under the Contract.

6.3 In addition to the termination rights under Articles 6.1 and 6.2 above, UNICEF can terminate the Contract at any time by providing written notice to the Supplier in any case in which UNICEF's mandate applicable to the performance of the Contract or UNICEF's funding applicable to the Contract is curtailed or terminated, whether in whole or in part. UNICEF can also terminate the Contract upon sixty (60) days' written notice to the Supplier without having to provide any justification.

6.4 As soon as it receives a notice of termination from UNICEF, the Supplier will immediately take steps to cease provision of the Goods in a prompt and orderly manner and to minimize costs and will seek instructions from UNICEF regarding Goods in transit (if any) and will not undertake any further or additional commitments as of and following the date it receives the termination notice. In addition, the Supplier will take any other action that may be necessary, or that UNICEF may direct in writing, for the minimization of losses and for the protection and preservation of any property (whether tangible or intangible) related to the Contract that is in the possession of the Supplier and in which UNICEF has or may be reasonably expected to acquire an interest.

6.5 If the Contract is terminated, no payment will be due from UNICEF to the Supplier except for Goods delivered in accordance with the requirements of the Contract and only if such Goods were ordered, requested or otherwise provided prior to the Supplier's receipt of notice of termination from UNICEF or, in the case of termination by the Supplier, the effective date of such termination. The Supplier will have no claim for any further payment beyond payments in accordance with this Article 6.5, but will remain liable to UNICEF for all loss or damages which may be suffered by UNICEF by reason of the Supplier's default (including but not limited to cost of the purchase and delivery of replacement or substitute goods).

6.6 The termination rights in this Article 6 are in addition to all other rights and remedies of UNICEF under the Contract.

Force Majeure

6.7 If one Party is rendered permanently unable, wholly or in part, by reason of force majeure to perform its obligations under the Contract, the other Party may terminate the Contract on the same terms and conditions as are provided for in Article 6.1 above, except that the period of notice will be seven (7) days instead of thirty (30) days. "Force majeure" means any unforeseeable and irresistible events arising from causes beyond the control of the Parties, including acts of nature, any act of war (whether declared or not), invasion, revolution, insurrection, terrorism or other acts of a similar nature or force. "Force majeure" does not include (a) any event which is caused by the negligence or intentional

action of a Party; (b) any event which a diligent party could reasonably have been expected to take into account and plan for at the time the Contract was entered into; (c) the insufficiency of funds, inability to make any payment required under the Contract, or any economic conditions, including but not limited to inflation, price escalations, or labour availability; or (d) any event resulting from harsh conditions or logistical challenges for the Supplier (including civil unrest) associated with locations at which UNICEF is operating or is about to operate or is withdrawing from, or any event resulting from UNICEF's humanitarian, emergency, or similar response operations.

7. ETHICAL STANDARDS

7.1 The Supplier will be responsible for the professional and technical competence of its Personnel including its employees and will select, for work under the Contract, reliable individuals who will perform effectively in the implementation of the Contract, respect the local laws and customs, and conform to a high standard of moral and ethical conduct.

7.2 (a) The Supplier represents and warrants that no official of UNICEF or of any United Nations System organisation has received from or on behalf of the Supplier, or will be offered by or on behalf of the Supplier, any direct or indirect benefit in connection with the Contract including the award of the Contract to the Supplier. Such direct or indirect benefit includes, but is not limited to, any gifts, favours or hospitality.

(b) The Supplier represents and warrants that the following requirements with regard to former UNICEF officials have been complied with and will be complied with:

(i) During the one (1) year period after an official has separated from UNICEF, the Supplier may not make a direct or indirect offer of employment to that former UNICEF official if that former UNICEF official was, during the three years prior to separating from UNICEF, involved in any aspect of a UNICEF procurement process in which the Supplier has participated.

(ii) During the two (2) year period after an official has separated from UNICEF, that former official may not, directly or indirectly on behalf of the Supplier, communicate with UNICEF, or present to UNICEF, about any matters that were within such former official's responsibilities while at UNICEF.

(c) The Supplier represents that, in respect of all aspects of the Contract (including the award of the Contract by UNICEF to the Supplier and the selection and awarding of sub-contracts by the Supplier), it has disclosed to UNICEF any situation that may constitute an actual or potential conflict of interest or could reasonably be perceived as a conflict of interest.

7.3 The Supplier further represents and warrants that neither it nor any of its Affiliates, or Personnel or directors, is subject to any sanction or temporary suspension imposed by any United Nations System organisation or other international inter-governmental organisation. The Supplier will immediately disclose to UNICEF if it or any of its Affiliates, or Personnel or directors, becomes subject to any such sanction or temporary suspension during the term of the Contract.

7.4 The Supplier will (a) observe the highest standard of ethics; (b) use its best efforts to protect UNICEF against fraud, in the performance of the Contract; and (c) comply with the applicable provisions of UNICEF's Policy Prohibiting and Combatting Fraud and Corruption. In particular, the Supplier will not engage, and will ensure that its Personnel, agents and sub-contractors do not engage, in

any corrupt, fraudulent, coercive, collusive or obstructive conduct as such terms are defined in UNICEF's Policy Prohibiting and Combatting Fraud and Corruption.

7.5 The Supplier will, during the term of the Contract, comply with (a) all laws, ordinances, rules and regulations bearing upon the performance of its obligations under the Contract and (b) the standards of conduct required under the UN Supplier Code of Conduct (available at the United Nations Global Marketplace website - www.ungm.org).

7.6 The Supplier further represents and warrants that neither it nor any of its Affiliates, is engaged, directly or indirectly, (a) in any practice inconsistent with the rights set out in the Convention on the Rights of the Child, including Article 32, or the International Labour Organisation's Convention Concerning the Prohibition and Immediate Action for the Elimination of the Worst Forms of Child Labour, No. 182 (1999); or (b) in the manufacture, sale, distribution, or use of anti-personnel mines or components utilised in the manufacture of anti-personnel mines.

7.7 The Supplier represents and warrants that it has taken and will take all appropriate measures to prevent sexual exploitation or abuse of anyone by its Personnel including its employees or any persons engaged by the Supplier to perform any services under the Contract. For these purposes, sexual activity with any person less than eighteen years of age, regardless of any laws relating to consent, will constitute the sexual exploitation and abuse of such person. In addition, the Supplier represents and warrants that it has taken and will take all appropriate measures to prohibit its Personnel including its employees or other persons engaged by the Supplier, from exchanging any money, goods, services, or other things of value, for sexual favours or activities or from engaging in any sexual activities that are exploitive or degrading to any person. This provision constitutes an essential term of the Contract and any breach of this representation and warranty will entitle UNICEF to terminate the Contract immediately upon notice to the Supplier, without any liability for termination charges or any other liability of any kind.

7.8 The Supplier will inform UNICEF as soon as it becomes aware of any incident or report that is inconsistent with the undertakings and confirmations provided in this Article 7.

7.9 The Supplier acknowledges and agrees that each of the provisions in this Article 7 constitutes an essential term of the Contract.

(a) UNICEF will be entitled, in its sole discretion and at its sole choice, to suspend or terminate the Contract and any other contract between UNICEF and the Supplier with immediate effect upon written notice to the Supplier if: (i) UNICEF becomes aware of any incident or report that is inconsistent with, or the Supplier breaches any of, the undertakings and confirmations provided in this Article 7 or the equivalent provisions of any contract between UNICEF and the Supplier or any of the Supplier's Affiliates, or (ii) the Supplier or any of its Affiliates, or Personnel or directors becomes subject to any sanction or temporary suspension described in Article 7.3 during the term of the Contract.

(b) In the case of suspension, if the Supplier takes appropriate action to address the relevant incident or breach to UNICEF's satisfaction within the period stipulated in the notice of suspension, UNICEF may lift the suspension by written notice to the Supplier and the Contract and all other affected contracts will resume in accordance with their terms. If, however, UNICEF is not satisfied that the matters are being adequately addressed by the Supplier, UNICEF may at any time, exercise its right to terminate the Contract and any other contract between UNICEF and the Supplier.

(c) Any suspension or termination under this Article 7 will be without any liability for termination or other charges or any other liability of any kind.

8. FULL COOPERATION WITH AUDITS AND INVESTIGATIONS

8.1 From time to time, UNICEF may conduct investigations relating to any aspect of the Contract including but not limited to the award of the Contract, the way in which the Contract operates or operated, and the Parties' performance of the Contract generally and including but not limited to the Supplier's compliance with the provisions of Article 7 above. The Supplier will provide its full and timely cooperation with any such inspections, post-payment audits or investigations, including (but not limited to) making its Personnel and any relevant data and documentation available for the purposes of such inspections, post-payment audits or investigations, at reasonable times and on reasonable conditions, and granting UNICEF and those undertaking such inspections, post-payment audits or investigations access to the Supplier's premises at reasonable times and on reasonable conditions in connection with making its Personnel and any relevant data and documentation available. The Supplier will require its sub-contractors and its agents, including, but not limited to, the Supplier's attorneys, accountants or other advisers, to provide reasonable cooperation with any inspections, post-payment audits or investigations carried out by UNICEF.

9. PRIVILEGES AND IMMUNITIES; SETTLEMENT OF DISPUTES

9.1 Nothing in or related to the Contract will be deemed a waiver, express or implied, deliberate or inadvertent, of any of the privileges and immunities of the United Nations, including UNICEF and its subsidiary organs, under the Convention on the Privileges and Immunities of the United Nations, 1946, or otherwise.

9.2 The terms of the Contract will be interpreted and applied without application of any system of national or sub-national law.

9.3 The Parties will use their best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to the Contract. Where the Parties wish to seek such an amicable settlement through conciliation, the conciliation will take place in accordance with the UNCITRAL Conciliation Rules then in force, or according to such other procedure as may be agreed between the Parties. Any dispute, controversy or claim between the Parties arising out of the Contract which is not resolved within ninety (90) days after one Party receives a request from the other Party for amicable settlement can be referred by either Party to arbitration. The arbitration will take place in accordance with the UNCITRAL Arbitration Rules then in force. The venue of the arbitration will be New York, NY, USA. The decisions of the arbitral tribunal will be based on general principles of international commercial law. The arbitral tribunal will have no authority to award punitive damages. In addition, the arbitral tribunal will have no authority to award interest in excess of the London Inter-Bank Offered Rate (LIBOR) then prevailing and any such interest will be simple interest only. The Parties will be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such controversy, claim or dispute.

10. NOTICES

10.1 Any notice, request or consent required or permitted to be given or made pursuant to the Contract will be in writing, and addressed to the persons listed in the Contract for the delivery of notices, requests or consents. Notices, requests or consents will be delivered in person, by registered mail, or by confirmed email transmission. Notices, requests or consents will be deemed received upon delivery (if

delivered in person), upon signature of receipt (if delivered by registered mail), or twenty-four (24) hours after confirmation of receipt is sent from the addressee's email address (if delivered by confirmed email transmission).

10.2 Any notice, document or receipt issued in connection with the Contract must be consistent with the terms and conditions of the Contract and, in case of any ambiguity, discrepancy or inconsistency, the terms and conditions of the Contract will prevail.

10.3 All documents that comprise the Contract, and all documents, notices and receipts issued or provided pursuant to or in connection with the Contract, will be deemed to include, and will be interpreted and applied consistently with, the provisions of Article 9 (Privileges and Immunities; Settlement of Disputes).

11. OTHER PROVISIONS

11.1 The Supplier acknowledges UNICEF's commitment to transparency as outlined in UNICEF's Information Disclosure Policy and confirms that it consents to UNICEF's public disclosure of the terms of the Contract should UNICEF so determine and by whatever means UNICEF determines.

11.2 The failure of one Party to object to or take affirmative action with respect to any conduct of the other Party which is in violation of the terms of the Contract will not constitute and will not be construed to be a waiver of the violation or breach, or of any future violation, breach or wrongful conduct.

11.3 The Supplier will be considered as having the legal status of an independent contractor as regards UNICEF. Nothing contained in the Contract will be construed as making the Parties principal and agent or joint venturers.

11.4 (a) Except as expressly provided in the Contract, the Supplier will be responsible at its sole cost for providing all the necessary personnel, equipment, material and supplies and for making all arrangements necessary for the performance of its obligations under the Contract.

(b) In the event that the Supplier requires the services of sub-contractors to perform any obligations under the Contract, the Supplier will notify UNICEF of this. The terms of any sub-contract will be subject to, and will be construed in a manner that is fully in accordance with, all of the terms and conditions of the Contract.

(c) The Supplier confirms that it has read UNICEF's Policy on Conduct Promoting the Protection and Safeguarding of Children. The Supplier will ensure that its Personnel understand the notification requirements expected of them and will establish and maintain appropriate measures to promote compliance with such requirements. The Supplier will further cooperate with UNICEF's implementation of this policy.

(d) The Supplier will be fully responsible and liable for all services performed by its Personnel and sub-contractors and for their compliance with the terms and conditions of the Contract. The Supplier's Personnel, including individual sub-contractors, will not be considered in any respect as being the employees or agents of UNICEF.

(e) Without limiting any other provisions of the Contract, the Supplier will be fully responsible and liable for, and UNICEF will not be liable for (i) all payments due to its Personnel and sub-contractors for their services in relation to the performance of the Contract; (ii) any action,

omission, negligence or misconduct of the Contractor, its Personnel and sub-contractors; (iii) any insurance coverage which may be necessary or desirable for the purpose of the Contract; (iv) the safety and security of the Contractor's Personnel and sub-contractors' personnel; or (v) any costs, expenses, or claims associated with any illness, injury, death or disability of the Contractor's Personnel and sub-contractors' personnel, it being understood that UNICEF will have no liability or responsibility with regard to any of the events referred to in this Article 11.4(d).

11.5 The Supplier will not, without the prior written consent of UNICEF, assign, transfer, pledge or make other disposition of the Contract, or of any part of the Contract, or of any of the Supplier's rights or obligations under the Contract.

11.6 No grant of time to by a Party to cure a default under the Contract, nor any delay or failure by a Party to exercise any other right or remedy available to it under the Contract, will be deemed to prejudice any rights or remedies available to it under the Contract or constitute a waiver of any rights or remedies available to it under the Contract.

11.7 The Supplier will not seek or file any lien, attachment or other encumbrance against any monies due or to become due under the Contract, and will not permit any other person to do so. It will immediately remove or obtain the removal of any lien, attachment or other encumbrance that is secured against any monies due or to become due under the Contract.

11.8 The Supplier will not advertise or otherwise make public for purposes of commercial advantage or goodwill that it has a contractual relationship with UNICEF or the United Nations. Except as regards references to the name of UNICEF for the purposes of annual reports or communication between the Parties and between the Supplier and its Personnel and sub-contractors, the Supplier will not, in any manner whatsoever use the name, emblem or official seal of UNICEF or the United Nations, or any abbreviation of the name of the United Nations, in connection with its business or otherwise without the written permission of UNICEF.

11.9 The Contract may be translated into languages other than English. The translated version of the Contract is for convenience only, and the English language version will govern in all circumstances.

11.10 No modification or change in the Contract, and no waiver of any of its provisions, nor any additional contractual relationship of any kind with the Supplier will be valid and enforceable against UNICEF unless set out in a written amendment to the Contract signed by an authorised official of UNICEF.

11.11 The provisions of Articles 2.8, 2.9, 3.8, 3.9, 4, 5, 7, 8, 9, 11.1, 11.2, 11.4(e), 11.6 and 11.8 will survive delivery of the Goods and the expiry or earlier termination of the Contract.

***

Annex B – WHO Model Inserts

MODEL INSERT
MEASLES VACCINE

DESCRIPTION

Measles vaccine is a live, attenuated viral vaccine. Each dose of 0.5 ml contains not less than.....(specify) CCID50 (cell culture infective doses 50%) of viral vaccine strain.....(specify), prepared in … (specify substrate: diploid cell (MRC5), chick embryo fibroblast)) and not more than .....µg of residual antibiotic (specify…). This vaccine is a freeze-dried product that must be reconstituted only with the sterile diluent provided separately for that purpose.

COMPOSITION	**Dose**
Volume	0.5 ml
Measles	XXX CCID50
Nature / amount of excipient	XX mg/ml
Nature / amount of stabilizer	XX mg/ml
Nature and amount of residual antibiotic	XX µg/ml

Diluent composition

ADMINISTRATION

Measles vaccine is generally injected subcutaneously. The preferred site of injection is the upper arm. The lyophilizate must be reconstituted by adding the entire content of the supplied container of diluent to the vaccine vial. The vaccine pellet should be completely dissolved in the diluent. Following reconstitution, the vaccine should be inspected visually for any foreign particulate matter prior to administration. If observed, the vaccine must be discarded.

A sterile needle and sterile syringe must be used for the reconstitution of the vaccine and for each injection. Because of sensitivity to ultraviolet light the vaccine must be stored in the dark at +2°C and +8°C and used within six (6) hours. Any opened vials remaining at the end of an immunization session (within six [6] hours of reconstitution) should be discarded. The vaccine vial monitor for this type of vaccine is attached to the vial cap and should be discarded when the vaccine is being reconstituted.
The diluent supplied is specially designed for use with this vaccine. Only this diluent may be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or for measles vaccine from other manufacturers. Using an incorrect diluent will result in damage to the vaccine and/or serious reactions to those receiving the vaccine. Diluent must not be frozen but must be cooled between +2°C and +8°C before used for reconstitution.

IMMUNIZATION SCHEDULE

In countries where the incidence and mortality from measles is high in the first year of life, the recommended age for vaccination against measles is at 9 months of age (270 days) or shortly after. In countries where infection occurs later in life (due to sustained high vaccination coverage), the age of vaccination can be moved to 12-15 months. It is recommended that all children have two (2) opportunities for measles immunization to

reduce the number both of unvaccinated children and of those who are vaccinated but fail to respond to the vaccine (primary vaccination failures). Although generally administered at school entry (4-6 years of age), the second opportunity for measles immunization may be provided as early as one (1) month following the first dose through routine or supplemental immunization activities. Measles vaccine can be given safely and effectively simultaneously with DTP, Td, TT, BCG, polio (OPV and IPV), *Haemophilus influenzae* type b, hepatitis B, or yellow fever vaccines or vitamin A supplementation.

SIDE EFFECTS

Side effects following measles vaccination, alone or in fixed combinations, are generally mild and transient. Slight pain and tenderness at the site of injection may occur within 24 hours of vaccination, sometimes followed by mild fever and local lymphadenopathy. About 7 - 12 days after vaccination up to 5% of measles vaccine recipients may experience fever > 39.4 °C for 1 - 2 days. A transient rash may occur in approximately 2% of vaccinees, usually starting 7-10 days following vaccination and lasting 2 days. Side effects, with the exception of anaphylactic reactions, are less likely to occur after receipt of a second dose of measles-containing vaccine. Encephalitis has been reported following measles vaccination at a frequency of approximately one (1) case per one (1) million doses administered although a causal link is not proven.

CONTRAINDICATIONS

There are few contraindications to the administration of measles vaccine. It is particularly important to immunize children with malnutrition. Persons with a history of an anaphylactic reaction to any component of the vaccine should not be vaccinated. Low grade fever, mild respiratory infections or diarrhoea, and other minor illnesses should not be considered as contraindications. Egg allergy is not considered to be a contraindication to vaccination. On theoretical grounds measles vaccine should also be avoided in pregnancy.

Immune deficiency

Children with known or suspected HIV infection are at increased risk of severe measles and should be offered measles vaccine as early as possible. The standard WHO recommendation for children at high risk of contracting measles is to immunize with measles vaccine at six (6) months of age, followed by an extra dose at nine (9) months. Measles vaccine is contraindicated in persons who are severely immunocompromised as a result of a congenital immune disorder, HIV infection, advanced leukaemia or lymphoma, serious malignant disease, or treatment with high-dose steroids, alkylating agents or anti-metabolites, or in persons who are receiving immunosuppressive therapeutic radiation.

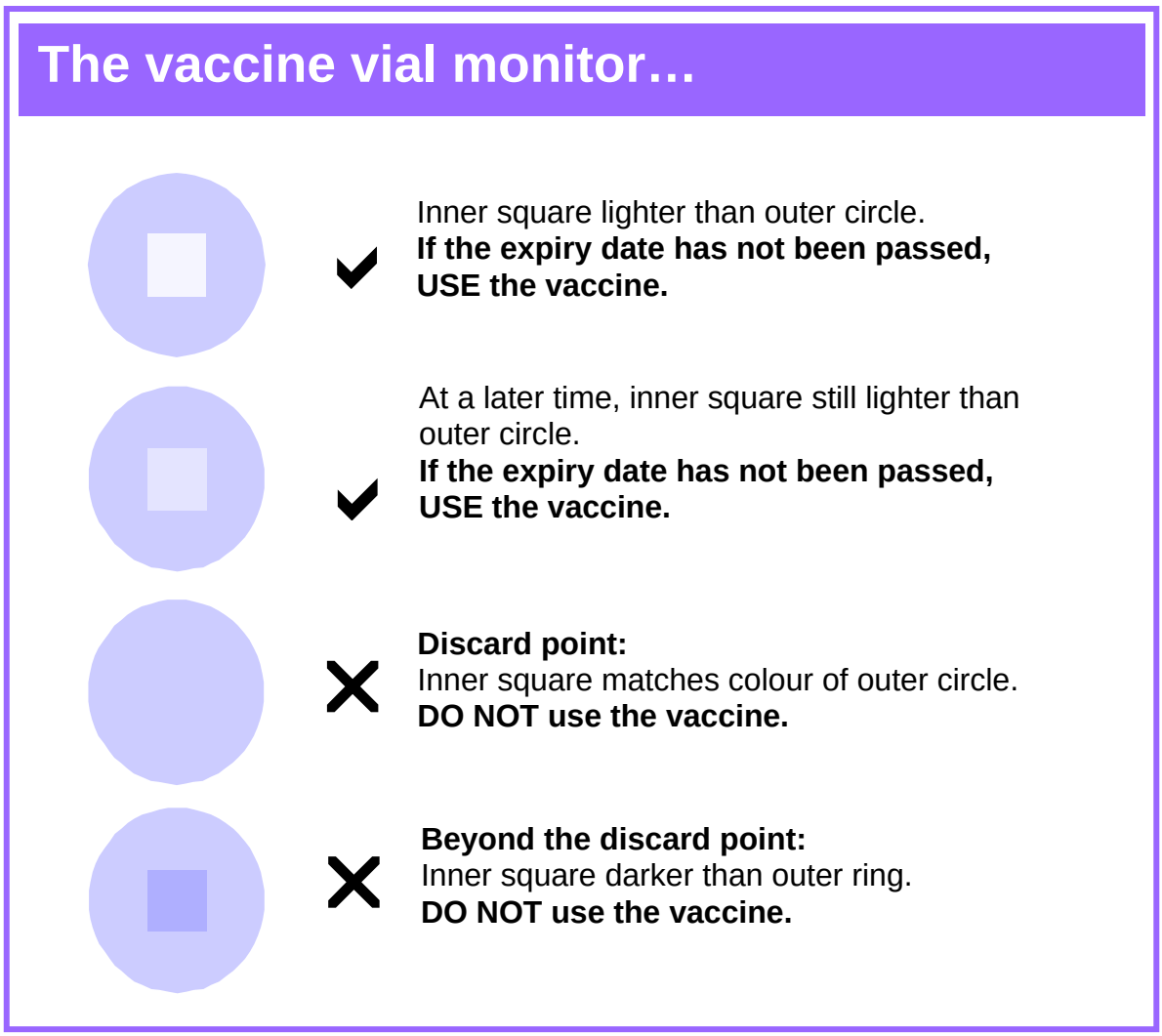
STORAGE

Freeze-dried measles vaccine should be kept in the refrigerator between +2°C and +8°C until used. The vials of vaccine and the diluent should be transported together, but the diluent must not be frozen. Because of sensitivity to ultraviolet light the vaccine must be stored in the dark

Freeze-dried measles vaccine should also be kept frozen at -20^{0}C

PRESENTATION
The vaccine comes in vials of .... dose (s).

Fig. The Vaccine Vial Monitor



The Vaccine Vial Monitors (VVMs) are on the cap of …….(specify vaccine) supplied through ……(specify supplier or manufacturer). The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

MODEL INSERT

MEASLES, MUMPS AND RUBELLA (MMR) COMBINED VACCINE

DESCRIPTION

The vaccine is a freeze-dried powder containing three viruses - measles, mumps and rubella.

a) The measles vaccine component is a live, attenuated viral vaccine. Each dose of 0.5 ml contains not less than.....(specify) CCID50 (cell culture infective doses 50%) of viral vaccine strain.....(specify), prepared in … (specify substrate: diploid cell (MRC5), chick embryo fibroblast cells) and not more than .....µg of residual antibiotic…… (specify)

b) The mumps vaccine component is an attenuated live virus vaccine. Each dose contains not less than.....(specify) CCID50 (cell culture infective doses 50%) of viral vaccine strain. .....(specify), prepared in … (specify substrate: diploid cell (MRC5), chick embryo fibroblast cells or embryonated eggs)) and not more than .....µg of residual antibiotic…. (specify).

b) The rubella vaccine component is also a live, attenuated viral vaccine. Each dose of 0.5 ml contains not less than.....(specify) CCID50 (cell culture infective doses 50%) of viral vaccine strain.....(specify), prepared in … (specify substrate: diploid cells, MRC5 / WI-38) and not more than .....µg of residual antibiotic….. (specify).

COMPOSITION	**Dose**
Volume	0.5 ml
Measles	XXX CCID50
Mumps	XXX CCID50
Rubella	XXX CCID50
Nature / amount of excipient	XX mg/ml
Nature / amount of stabilizer	XX mg/ml
Nature and amount of residual antibiotic	XX µg/ml

Diluent composition

ADMINISTRATION

Immunization consists of a single dose of 0.5 ml injected subcutaneously, preferably in the upper arm. The lyophilizate must be reconstituted by adding the entire content of the supplied container of diluent to the vaccine vial. The vaccine pellet should be completely dissolved in the diluent. Following reconstitution, the vaccine should be inspected visually for any foreign particulate matter prior to administration. If observed, the vaccine must be discarded.

A sterile needle and sterile syringe must be used for the reconstitution of the vaccine and for each injection.
Because of sensitivity to ultraviolet light, the vaccine must be stored in the dark at +2°C and +8°C and used within six (6) hours. Any opened vials remaining at the end of an immunization session (within six [6] hours of reconstitution should be discarded. The vaccine vial monitor for this type of vaccine is attached to the vial cap and should be discarded when the vaccine is being reconstituted.
The diluent supplied is specially designed for use with this vaccine. Only this diluent may be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or for measles vaccine from other manufacturers. Using an incorrect diluent will result in damage to the vaccine and/or serious reactions to those receiving the vaccine. Diluent must not be frozen but must be cooled between +2°C and +8°C before used for reconstitution.

IMMUNIZATION SCHEDULE

In countries where the incidence and mortality from measles is high in the first year of life, the recommended age for immunization using MMR is at 9 months of age (270 days) or soon after. In countries where measles infection occurs later in life (due to sustained high vaccine coverage), the age of immunization can be moved to 12-15 months. A second opportunity is needed both to increase the chance that every child receives at least one dose of measles-containing vaccine and to increase the proportion of the population that is fully immunized. The second dose of measles-containing vaccine can be given through routine or supplemental activities.

MMR vaccine can be given safely and effectively simultaneously with DTP, Td, TT, BCG, polio (OPV and IPV), *Haemophilus influenzae* type b, hepatitis B,or yellow fever vaccines or vitamin A supplementation.

The combination MMR vaccine produces an immunological response to each antigen (e.g. measles, mumps, rubella) equivalent to that following administration of each of the single antigen products. The safety and immunogenicity of this combination vaccine appears to be similar to that of its individual constituents.

SIDE EFFECTS

The type and rate of severe adverse reactions with the combined MMR vaccine do not differ significantly from the measles, mumps and rubella vaccine reactions described separately.
- *Side effects following measles vaccination* are generally mild and transient. Slight pain and tenderness at the site of injection may occur within 24 hours of vaccination, sometimes followed by mild fever and local lymphadenopathy. About 7 - 12 days after vaccination up to 5% of measles vaccine recipients may experience fever > 39.4 °C for 1 - 2 days. A transient rash may occur in approximately 2% of vaccinees, usually starting 7-10 days following vaccination and lasting 2 days. Side effects, with the exception of anaphylactic reactions, are less likely to occur after receipt of a second dose of measles-containing vaccine. Encephalitis has been reported following measles vaccination at a frequency of approximately one (1) case per one (1) million doses administered although a causal link is not proven.

- *The mumps component* may result in parotitis in up to 3% of recipients, and the onset is usually 5-24 days following vaccination. Orchitis occurs rarely. Aseptic meningitis, with onset 15-35 days following vaccination, has been reported at widely varying frequencies. The delayed onset of aseptic meningitis may limit the ability to detect these cases by passive surveillance. Vaccine-associated aseptic meningitis resolves spontaneously in less than one week without sequelae. The risk of developing aseptic meningitis may vary with the mumps vaccine strain. However, the available data are not strong enough to form the basis of a recommendation not to use the specific strain. It was noted that higher rates of aseptic meningitides have been described for the Urabe, the Leningrad-Zagreb and the Leningrad- 3 strain vaccines compared with the Jeryl-Lynn strain vaccine. The possible basis for this difference and /or the other characteristics of the product that might explain these differences are not known. Some of the variability observed in the risk of aseptic meningitides following use of the various mumps vaccine strains may reflect pre-immunity, in particular in older age groups, as well as the variable levels of sensitivity of surveillance and of diagnostic practices in different settings.

- *The rubella component* may commonly result in transient arthralgias (25%) and arthritis (10%) among adolescent and adult females that begin 1-3 weeks after vaccination and last from 1 day to 2 weeks. However, arthralgias and arthritis are very rare in children and in men receiving MMR vaccine (0% -3%). These transient reactions seem to occur in non-immunes only, for whom the vaccine is important. Low grade fever and rash, lymphadenopathy, myalgia and paraesthesiae are commonly reported. Thrombocytopenia is rare and has been reported in less than 1 case per 30 000 doses administered. Anaphylactic reactions are also rare.

CONTRAINDICATIONS

A previous allergic reaction to measles, MR or MMR vaccine is a contraindication. Persons with a history of an anaphylactic reaction to any components of the vaccine should not be vaccinated.

Apart from this, there are few contraindications to the administration of MMR vaccine. It is particularly important to immunize children with malnutrition. Low-grade fever, mild respiratory infections or diarrhoea, and other minor illnesses should not be considered as contraindications.

MMR vaccine should not be administered during pregnancy because of the theoretical but never demonstrated teratogenic risk. Inadvertent receipt of MMR vaccine during pregnancy is not an indication for an abortion. If pregnancy is planned, then an interval of one month should be observed after MMR vaccination.

Immune deficiency

Children with known or suspected HIV infection are at increased risk of severe measles. Such children should be offered measles vaccine as early as possible. The standard WHO recommendation for children at high risk of contracting measles is to immunize with measles vaccine at 6 months of age with a second dose at 9 months. This recommendation should be applied to children with known or suspected HIV infection. The vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukaemia, lymphoma or generalized malignancy.

STORAGE

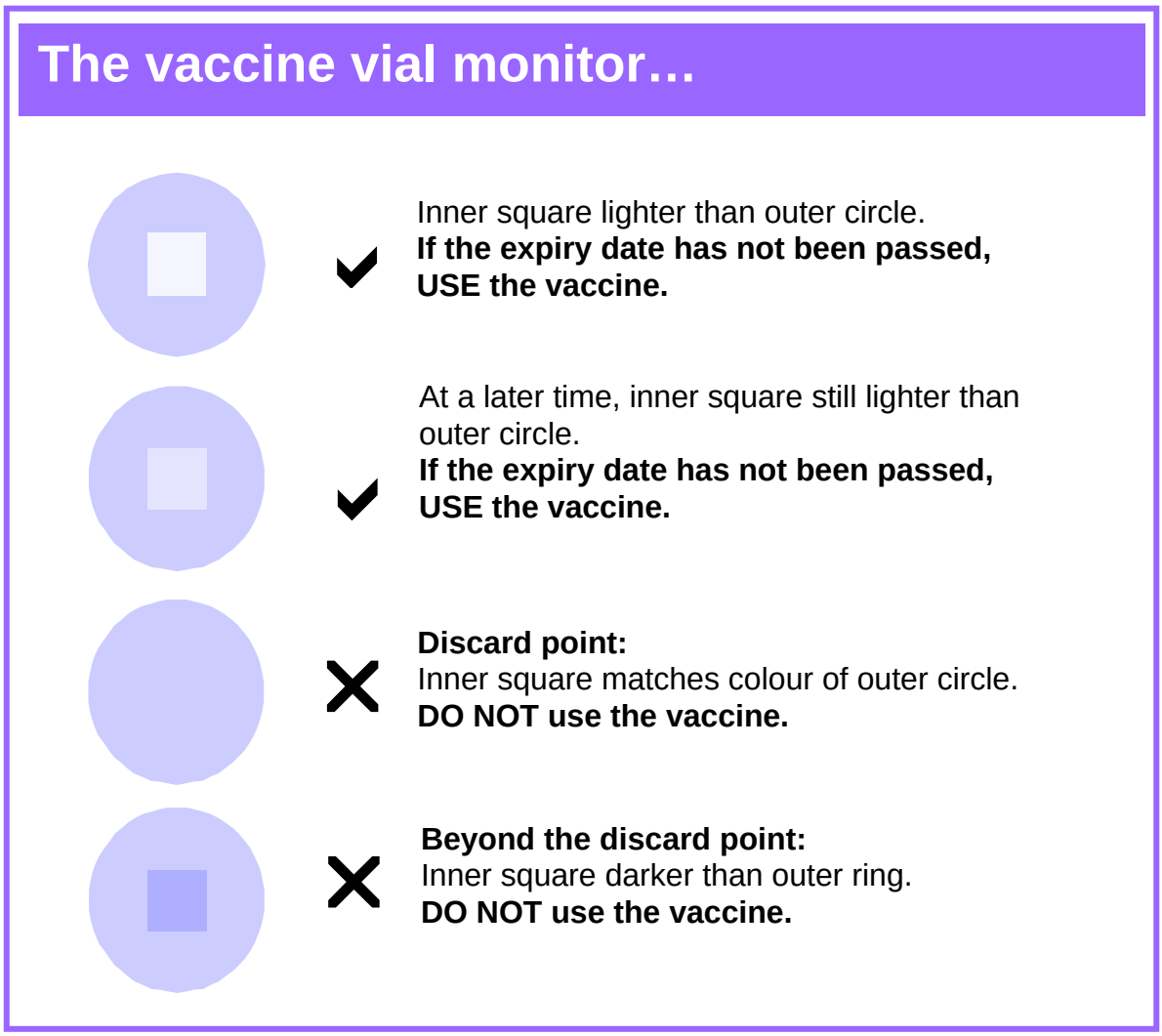
Freeze-dried MMR vaccine should be kept in the refrigerator between +2°C and +8°C until used. The vials of vaccine and the diluent should be transported together, but the diluent must not be frozen. Because of sensitivity to ultraviolet light the vaccine must be stored in the dark

Freeze-dried measles vaccine should also be kept frozen at -20^{0}C

PRESENTATION

The vaccine comes in vials of .... dose (s).

Fig. The Vaccine Vial Monitor



The Vaccine Vial Monitors (VVMs) are on the cap of …….(specify vaccine) supplied through ……(specify supplier or manufacturer). The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

MODEL INSERT
MEASLES AND RUBELLA (MR) COMBINED VACCINE

DESCRIPTION

The vaccine is a freeze-dried powder containing two antigens - measles and rubella. It must be reconstituted only with the sterile diluent provided for that purpose.

a) The measles vaccine component is a live, attenuated viral vaccine. Each dose of 0.5 ml contains not less than.....(specify) CCID50 (cell culture infective doses 50%) of viral vaccine strain.....(specify), prepared in … (specify substrate: diploid cell (MRC5) or chick embryo fibroblast cells) and not more than .....µg of residual antibiotic…. (specify).

b) The rubella vaccine component is also a live, attenuated viral vaccine. Each dose of this vaccine contains a defined number of active virus particles (>1000 CCID50) culture infective doses 50%) of viral vaccine strain.....(specify), prepared in … (specify substrate: diploid cells, MRC5 / WI-38) and not more than .....µg of residual antibiotic….. (specify).

COMPOSITION	**Dose**
Volume	0.5 ml
Measles	XXX CCID50
Rubella	XXX CCID50
Nature / amount of excipient	XX mg/ml
Nature / amount of stabilizer	XX mg/ml
Nature and amount of residual antibiotic	XX mg/ml

Diluent composition

ADMINISTRATION

MR vaccine is generally injected subcutaneously. The preferred site of injection is the upper arm. The lyophilizate must be reconstituted by adding the entire content of the supplied container of diluent to the vaccine vial. The vaccine pellet should be completely dissolved in the diluent. Following reconstitution, the vaccine should be inspected visually for any foreign particulate matter prior to administration. If observed, the vaccine must be discarded.

A sterile needle and sterile syringe must be used for the reconstitution of the vaccine and for each injection. Because of sensitivity to ultraviolet light, the vaccine must be stored in the dark at +2°C and +8°C and used within six (6) hours. Any opened vials remaining at the end of an immunization session (within six [6] hours of reconstitution) should be discarded. The vaccine vial monitor for this type of vaccine is attached to the vial cap and should be discarded when the vaccine is being reconstituted.

The diluent supplied is specially designed for use with this vaccine. Only this diluent may be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or for measles vaccine from other manufacturers. Using an incorrect diluent will result in

damage to the vaccine and/or serious reactions to those receiving the vaccine. Diluent must not be frozen but must be cooled between +2°C and +8°C before used for reconstitution .

IMMUNIZATION SCHEDULE

In countries where the incidence and mortality from measles is high in the first year of life, the recommended age for vaccination against measles is at 9 months of age (270 days) or shortly after. In countries where infection occurs later in life (due to sustained high vaccination coverage), the age of vaccination can be moved to 12-15 months. It is recommended that all children have two (2) opportunities for immunization with a measles-containing vaccine to reduce the number both of unvaccinated children and of those who are vaccinated but fail to respond to the vaccine (primary vaccination failures). The second dose of measles-containing vaccine may be provided as early as one (1) month following the first dose through routine or supplemental immunization activities. The vaccine can be given safely and effectively simultaneously with DTP, Td, TT, BCG, polio (OPV and IPV), *Haemophilus influenzae* type b, hepatitis B, or yellow fever vaccines or vitamin A supplementation.

The combination vaccine produces an immunological response to each antigen equivalent to that following administration of each of the single antigen products. The safety and immunogenicity of this combination vaccine appears to be similar to that of its individual components.

SIDE EFFECTS

Side effects following MR vaccination are mostly mild and transient, and are similar in frequency and severity to those following administration of each of the single antigen products.

Side effects following measles vaccination are generally mild and transient. Slight pain and tenderness at the site of injection may occur within 24 hours of vaccination, sometimes followed by mild fever and local lymphadenopathy. About 7 - 12 days after vaccination up to 5% of measles vaccine recipients may experience fever > 39.4 °C for 1 - 2 days. A transient rash may occur in approximately 2% of vaccinees, usually starting 7-10 days following vaccination and lasting 2 days. Side effects, with the exception of anaphylactic reactions, are less likely to occur after receipt of a second dose of measles-containing vaccine. Encephalitis has been reported following measles vaccination at a frequency of approximately one (1) case per one (1) million doses administered although a causal link is not proven.

Side effects following vaccination with rubella vaccine are also mild, particularly in children. Common side effects include pain, redness and induration at the site of injection. Low-grade fever and rash, lymphadenopathy, myalgia and paraesthesia are commonly reported. Joint symptoms tend to be rare in children (0% -3%) and in men, but are common among vaccinated adolescents and adult females; they include arthralgias (25%) and arthritis (10%) that usually last from a few days to two (2) weeks. These transient reactions seem to occur in non-immune individuals only, for whom the vaccine is important. Thrombocytopenia is rare and has been reported in less than 1 case per 30,000 doses administered. Anaphylactic reactions are also rare.

CONTRAINDICATIONS

A previous allergic reaction to measles or MR vaccine is a contraindication. Persons with a history of an anaphylactic reaction to any components of the vaccine should not be vaccinated. Apart from these, there are few contraindications to the administration of MR vaccine. It is particularly important to immunize children with malnutrition. Low-grade fever, mild respiratory infections or diarrhoea, and other minor illnesses should not be considered as contraindications. On theoretical grounds measles vaccine should also be avoided in pregnancy. *Rubella vaccination should be avoided in pregnancy because of the theoretical (but never demonstrated) teratogenic risk. If pregnancy is being planned, then an interval of one (1) month should be observed after rubella immunization. No serious cases have been reported in more than 1000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy. Rubella vaccination during pregnancy is not an indication for abortion.*

Immune deficiency

Children with known or suspected HIV infection are at increased risk of severe measles and should be offered measles vaccine as early as possible. The standard WHO recommendation for children at high risk of contracting measles is to immunize with measles vaccine at six (6) months of age, followed by an extra dose at nine (9) months. The vaccine is contraindicated in persons who are severely immunocompromised as a result of congenital disease, HIV infection, advanced leukaemia or lymphoma, serious malignant disease, or treatment with high-dose steroids, alkylating agents or anti-metabolites, or in persons who are receiving immunosuppressive therapeutic radiation.

STORAGE

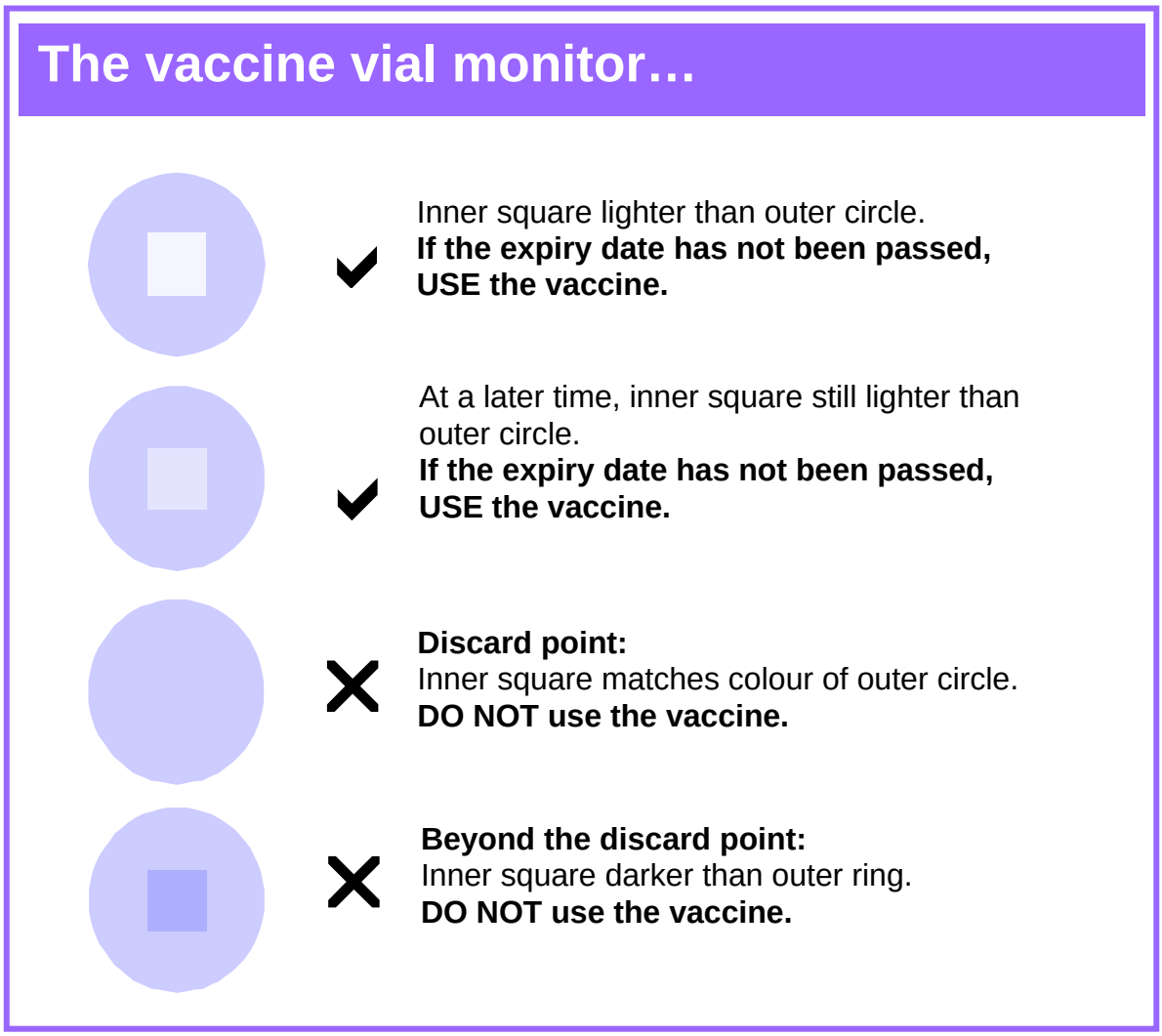
Freeze-dried MR vaccine should be kept in the refrigerator between +2°C and +8°C until used. The vials of vaccine and the diluent should be transported together, but the diluent must not be frozen. Because of sensitivity to ultraviolet light the vaccine must be stored in the dark

Freeze-dried measles vaccine should also be kept frozen at -20^0C

PRESENTATION

The vaccine comes in vials of .... dose(s).

Fig. The Vaccine Vial Monitor



The Vaccine Vial Monitors (VVMs) are on the cap of …….(specify vaccine) supplied through ……(specify supplier or manufacturer). The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.