



GAVI/13/174/sc/cw

The Minister of Health and Social Welfare
Ministry of Health and Social Welfare
P.O. Box 9083
Dar-es-Salaam
United Republic of Tanzania

09 April 2013

Dear Minister,

Tanzania's Proposal to the GAVI Alliance for Measles Second Dose vaccine

I am writing in relation to Tanzania's proposal to the GAVI Alliance for New Vaccines Support for measles second dose vaccine, which was submitted to the GAVI Secretariat in August 2012.

Following a meeting of the GAVI Executive Committee on 15 February 2013 to consider the recommendations of the Independent Review Committee (IRC), I am pleased to inform you that Tanzania has been approved with clarifications for measles second dose vaccine support as specified in the appendices to this letter.

In relation to your proposal for Measles second dose vaccine, I confirm that Tanzania has provided a satisfactory response to the clarifications that were required by the IRC.

Measles second dose vaccine is exempt from co-financing.

For your information, this document contains the following important attachments:

- Appendix A: Description of approved GAVI support to Tanzania
- Appendix B: Financial and programmatic information
- Appendix C: A summary of the IRC Report
- Appendix D: The terms and conditions of GAVI Alliance support

The GAVI Alliance has recently sent you a new Partnership Framework Agreement (PFA) designed to improve the ease and efficiency for countries to understand the GAVI requirements, all in one clear and standardised document. For ease of reference, the PFA will include appendices in the same format as Appendix B.

The following table summarises the outcome for each type of GAVI support applicable to Tanzania:

New Vaccines Support <i>Type of vaccine</i>	Approved for the first year	Approved for the second year
Measles Second Dose	US\$ 806,000	n/a
MSD Vaccine Introduction Grant	US\$ 1,626,000	n/a

Please do not hesitate to contact my colleague Charlie Whetham cwhetham@gavialliance.org if you have any questions or concerns.

Yours sincerely,



Hind Khatib-Othman
Managing Director, Country Programmes

cc: The Minister of Finance
 The Director of Medical Services
 Director Planning Unit, MoH
 The EPI Manager
 WHO Country Representative
 UNICEF Country Representative
 Regional Working Group
 WHO HQ
 UNICEF Programme Division
 UNICEF Supply Division
 The World Bank

Appendix A

Description of GAVI support to *Tanzania* (the "Country")

New Vaccines Support (NVS)

The GAVI Alliance has approved the Country's request for supply of vaccine doses and related injection safety material which are estimated to be required for the 2014 and 2015 immunization programme as set out in Appendix B. Financing provided by GAVI for vaccines will be in accordance with:

- The GAVI Alliance Guidelines governing Tanzania's proposal application; and
- The final proposal as approved by the IRC, including any subsequent clarifications.

The vaccines provided will be used for routine immunisation of children under 12 months of age. The principles of the WHO-UNICEF-UNFPA joint statement on safety of injections (WHO/V&B/99.25) shall apply to all immunisation provided with these vaccines.

Item number 11 of Appendix B summarises the details of the approved GAVI support for vaccines in 2013 and 2014.

Any required taxes, customs, toll or other duties imposed on the importation of vaccines and related supplies cannot be paid for using GAVI funding.

GAVI is not responsible for any liability that may arise in connection with the distribution or use of vaccines and related supplies after title to such vaccines and related supplies has passed to the country, excluding liability for any defect in vaccines and related supplies, which remain the responsibility of the applicable manufacturer.

Measles second dose vaccine is exempt from co-financing.

GAVI support will only be provided if the Country complies with the following requirements:

Transparency and Accountability Policy(TAP): Compliance with any TAP requirements pursuant to the GAVI TAP Policy and the requirements under any Aide Memoire concluded between GAVI and the country.

Financial Statements & External Audits: Compliance with the then-current GAVI requirements relating to financial statements and external audits.

Grant Terms and Conditions: Compliance with GAVI's standard grant terms and conditions (attached in Appendix D).

Country Co-financing: GAVI must receive proof of country co-payment from the Country such as invoices or shipment receipts if neither UNICEF nor PAHO is the procurement agent for country co-financed vaccine for the prior calendar year.

Monitoring and Annual Progress Reports: Tanzania's use of financial support for the introduction of new vaccinations with Measles second dose vaccine is subject to strict performance monitoring. The GAVI Alliance uses country systems for monitoring and auditing

performance as well as other data sources including WHO/UNICEF immunization coverage estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunised and the delivery of funds to co-finance the vaccine.

Tanzania will report on the achievements and request support for the following year in the Annual Progress Report (APR). The APR must contain information on the number of children reported to have been vaccinated with DTP3 and 3 doses of pentavalent vaccine by age 12 months, based on district monthly reports reviewed by the ICC, and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). The APRs will also contain information on country's compliance with the co-financing arrangements outlined in this letter. APRs endorsed by the ICC, should be sent to the GAVI Secretariat no later than 15 May every year. Continued funding beyond what is being approved in this letter is conditional upon receipt of satisfactory Annual Progress Reports and availability of funds.

MEASLES SECOND DOSE VACCINE SUPPORT

This Decision Letter sets out the Programme Terms

1. Country: Tanzania												
2. Grant Number: 1415-TZA-09a-X / 14-TZA-08d-Y												
3. Decision Letter no: 2												
4. Date of the Partnership Framework Agreement: N/A												
5. Programme Title: New Vaccine Support												
6. Vaccine type: Measles second dose												
7. Requested product presentation and formulation of vaccine: Measles, 10 dose(s) per vial, LYOPHILISED												
8. Programme Duration¹: 2014 - 2015												
9. Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement)												
<table border="1"> <thead> <tr> <th></th> <th>2014</th> <th>2015</th> <th>2016</th> <th>2017</th> <th>Total²</th> </tr> </thead> <tbody> <tr> <td>Programme Budget (US\$)</td> <td>US\$806,000</td> <td>US\$702,000</td> <td>-</td> <td>-</td> <td>US\$1,508,000</td> </tr> </tbody> </table>		2014	2015	2016	2017	Total ²	Programme Budget (US\$)	US\$806,000	US\$702,000	-	-	US\$1,508,000
	2014	2015	2016	2017	Total ²							
Programme Budget (US\$)	US\$806,000	US\$702,000	-	-	US\$1,508,000							
10. Vaccine Introduction Grant: US\$ 1,626,000 payable up to 6 months before the introduction												
11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):³												
<table border="1"> <thead> <tr> <th>Type of supplies to be purchased with GAVI funds in each year</th> <th>2014</th> </tr> </thead> <tbody> <tr> <td>Number of Measles second dose vaccines doses</td> <td>2,419,400</td> </tr> <tr> <td>Number of AD syringes</td> <td>2,152,500</td> </tr> <tr> <td>Number of re-constitution syringes</td> <td>268,600</td> </tr> <tr> <td>Number of safety boxes</td> <td>26,875</td> </tr> <tr> <td>Annual Amounts (US\$)</td> <td>US\$806,000</td> </tr> </tbody> </table>	Type of supplies to be purchased with GAVI funds in each year	2014	Number of Measles second dose vaccines doses	2,419,400	Number of AD syringes	2,152,500	Number of re-constitution syringes	268,600	Number of safety boxes	26,875	Annual Amounts (US\$)	US\$806,000
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Annual Amounts (US\$)	US\$806,000											
12. Procurement agency: UNICEF												
13. Self-procurement: N/A												

¹ This is the entire duration of the programme.

² This is the total amount endorsed by GAVI for the entire duration of the programme. This should be equal to the total of all sums in the table.

³ This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently. *Ceci est le montant approuvé par GAVI. Prière de modifier les montants annuels indicatifs des années précédentes si cela change ultérieurement*

14. Co-financing obligations: Measles second dose vaccine is exempt from co-financing.
15. Operational support for campaigns: N/A
16. Additional documents to be delivered for future disbursements: N/A
17. Clarifications: Tanzania has provided a satisfactory response to the clarifications required.
18. Other conditions: N/A

Signed by
On behalf of the GAVI Alliance



Hind Khatib-Othman
Managing Director, Country Programmes
08 April 2013

Appendix C

IRC NVS COUNTRY REPORT

Geneva, 8th – 19th October 2012

Type of support requested: NVS
Vaccines requested: Measles Second Dose

Country profile/Basic data (2012)

Population	47,656,367	Infant mortality rate (year)	54.6/1000%
Birth cohort	1,964,513	Govt. Health expenditure	5%
Surviving infants	1,857,274	GNI/capita (year)	\$540
DTP3 coverage	90% (WHO)	Co-financing country group*	Low-income

*low income, intermediate or graduating

There are some discrepancies between population statistics from WHO data and the proposal (data from National Bureau of Statistics gives total population of 44,497,102 and the number of surviving infants as 1,714,246).

1. Type of support requested/Total funding/Implementation period

Tanzania requests 4,545,000 doses of measles vaccine (10 dose / vial lyophilised) for routine measles second dose (MSD). The implementation period is 2014-2015. National launch is planned for January 2014. Funds requested include US\$ 779,000 in 2014 and US\$ 679,000 in 2015 for vaccine and injection materials (total US\$ 1,458,000) and an NVS Introduction Grant of US\$ 1,625,546 for introduction activities at US\$ 0.8 per per child in the birth cohort. Note that total costs for vaccine introduction vary from US\$ 1,625,546 to US\$ 5,813,083 in the different documents. No co-funding is required for this vaccine. The country is aiming for 75.2% coverage in 2014 and 78.9% in 2015.

2. History of GAVI support

GAVI support to Tanzania started in 2001.

Table 1. NVS and INS Support

NVS and INS support	Approval Period
INS	2003-2005
DPT-HepB	2001-2015
DTP-HepB-Hib	2009-2015
Pneumococcal (PCV13)	2012-2015
Rotavirus	2012-2015

Table 2. Cash Support

Cash support	Approval Period
ISS	2001-2010

3. Composition & Functioning of the ICC

The ICC was established in 1995. Members come from the MOHSW, Ministry of Finance, WHO, USAID, Kreditanstalt für Wiederaufbau (KfW), Tanzania Red Cross Society (TRCS), CIDA, Christian Social Services Commission (CSSC). It meets quarterly and its functions are to foster partnerships, review and approve immunization workplans, review use of funds and address issues to strengthen immunization. One set of ICC meeting minutes (23 August 2012) are provided. The proposal for introduction of measles second dose (MSD) was approved by the Minister of Health and Finance and the ICC members. No NITAG has been established in Tanzania.

4. Status of the National Immunisation Programme

(a) Programme overview

Support for EPI Tanzania comes from WHO and UNICEF, with CIDA providing cold chain capacity support. SIA-related support also comes from Red Cross Society, faith-based organisations and the MOE. The Tanzanian government pays for the traditional EPI vaccines (BGC, OPV, Measles 1 and TT). Tanzania introduced Hepatitis B vaccine in 2002 and the pentavalent vaccine (co-financed by GAVI) in April 2009. Weaknesses identified in the introduction of pentavalent vaccine included cold storage capacity (vaccine shipments had to be increased from 3 to 8 shipments per year), late distribution of IEC and training materials, a late vaccine launch, incomplete data collection tools, insufficient numbers of trained staff, stock-outs of vaccine, issues with denominators and inadequate disposal of injection waste. Despite this, the coverage of pentavalent vaccine was 91% in 2010.

Tanzania will introduce rotavirus and pneumococcal vaccine into routine infant immunisations in early 2013. The country had 92% coverage of DTP3 and 95% coverage of measles dose 1 in 2011 and has maintained MCV1 coverage >80% since 2004.

Justification for the introduction of MSD was given in the proposal and the Introduction Plan. The introduction of MSD is in line with the cMYP 2010-2015. From the Global Measles Assessment Mortality document (2000-2008), Tanzania reports a measles incidence of 6.2/100,000. 1,582 cases were reported in 2011, of which 74% were unvaccinated. A study to examine risk factors related to the measles outbreak in Tanzania between 2006 and 2007 showed that vaccine effectiveness was 95% for 2 doses c.f. 88% for one dose.

(b) Gender and equity issues

Gender has not been addressed as part of the application, as the country says evidence from the 2010 DHS shows no gender barriers to immunisation services e.g. DTP3 coverage for males was 88.2% and for females 87.8%. Equity is not addressed. It would have been helpful to have socio-demographic details and a map of the distribution of measles cases by the 3 categories, vaccinated, not vaccinated and unknown, in the survey of measles cases described above. The country does not currently routinely report on sex-disaggregated data but it is stated in the proposal that the health management information system data collection tool is being revised to include sex-disaggregated data.

5. Comprehensive Multi Year Plan (cMYP) overview

The cMYP (2010-2015) covers the proposed request for new vaccines. Tanzania is committed to achieving 98% mortality reduction from measles by 2012 and to reduce measles incidence to <5 cases/10⁶ population/year at national level, and has signed up to address the MDGs 4, 5 and 6 within a Joint Action Plan (JAP). Measles-based case

vaccine temperature storage (50%), storage capacity (61%) and distribution (34%). Recommendations to address the problems were laid out in the report. It has been recommended for the National vaccine store to conduct a temperature monitoring study and for all WICRs and WIFRs to have a continuous temperature recorder.

8. Cold chain capacity

The proposal does not anticipate any problems with cold chain capacity for MSD introduction. The national vaccine storage capacity was estimated based on 6 months, plus 25% buffer stock, excluding the eight new WICRs that have not yet been installed. When these have been installed and commissioned, hopefully prior to the introduction of new vaccines (Rota and PCV10), the National and Regional storage capacity will be sufficient. UNICEF SD has supported Tanzania with the procurement and installation of cold chain equipment in 2011. This will definitely increase the vaccine storage capacity of the district and health facility levels. In March 2012 UNICEF Supply Division issued an order for installation of the remaining 26 cold rooms to be installed in the whole of the country. That project is still in progress and expected to be completed by the end of 2012. In August 2012 UNICEF SD placed another order for a cold room of 30 m³.

9. Financial Analysis

Inconsistencies in the total costs for vaccine and injection supplies and for the costs of vaccine introduction were seen in the proposal and across several documents. Using a factor of US\$ 0.8 per child in the birth cohort, the introduction grant requested from GAVI (US\$ 1,625,546) is correct. A timeline of activities was supplied, but seems to apply to 2013 and 2014. The full cost of the introduction was estimated in one part of the proposal to be US\$ 5,813,083, therefore the GAVI contribution to the introduction grant accounts for 28% of introduction costs. Key costs included for GAVI are training (54%), advocacy (26%) and transport/vehicles (10%). A detailed outline of cost items and sources of finance was not provided with the application. The number of trainings, unit costs, and financing were not provided. In terms of transport, the Monitoring IRC 2012 noted "issues like the lack of transport to almost all district is not addressed due to financial gaps; this will have to be addressed as vehicles are needed to facilitate the distribution of vaccine, outreach services and supportive supervision". Expenditure in this area therefore appears to be required.

The cMYP report is for the period 2012-2016 (although front page states 2010-2015) and the spreadsheet appears to match this 2012-2016 time period. It is not clear how the 2nd dose has been included in the cost projections spreadsheet, although a measles line is evident. The introduction plan noted "The budget for training is not ring-fenced and this hampers refresher training" – which could be challenge - given US\$ 1,518,402 of the training budget for the introduction is being financed by government and other (non-GAVI) sources in Tanzania.

Tanzania has developed a Medium Term Expenditure Framework (MTEF) for the next three years, which should provide some guarantee that EPI funding will be stable in the medium term.

The Government funds traditional antigens. It is observed that allocation of funding to EPI at central level has been declining over the past three Financial Years, 2007/08 – 2009/10, despite the increasing allocation to the health sector" (Section 2.6.2 of cMYP Report). The 2012 Monitoring IRC further stated that "the country anticipates financial shortfalls due the global downturn and the internal financial cutbacks of 26% for the 2012/13 financial year. This is expected to affect traditional vaccine and its related injection supplies".

10. Co-financing arrangements

Co-financing is not a requirement for MSD and no co-financing has been proposed.

The 2012 Monitoring IRC stated "The country still needs to provide a financial statement for NVS introduction grant disbursed by GAVI in 2008 showing the economic classification of expenditures and confirming the closing balance". There has been so far no progress in receiving the necessary clarifications needed to be able to prepare the Aide Memoire, namely whether all expenditures will be executed centrally or whether funds will be disbursed to local levels for locally executed activities.

11. Consistency across proposal documents

There are discrepancies in the total costs to introduce the vaccine between the proposal (total US\$ 5,813,083, of which US\$ 1,625,546 is requested from GAVI, leaving a shortfall of US\$ 4,187,537) and the Introduction Plan (US\$ 1,625,546, of which US\$ 52,156 are described as being unfunded). There were also inconsistencies within the proposal itself for vaccine and injection materials: US\$ 5,646,375 in 2014 and US\$ 4,847,450 in 2015 in the executive summary, versus US\$ 779,000 and US\$ 679,000 in Annex 1.1.b. These are substantial differences that affect the potential budget shortfall. There were minor discrepancies in the Improvement Plan and proposal in terms of number of shipments per year (8 versus 12) for pentavalent vaccine and in the itemised line item costs for vaccine introduction in the two documents. The Improvement Plan showed a timeline for pneumococcal and rotavirus vaccine. The cMYP refers to introduction of HPV vaccine in addition to MSD but HPV is not included in this proposal. In the VIP, the target for 2014 is set at 80%, as opposed to 75% in the GAVI application. In addition, the estimated vaccine wastage factor in the VIP is set at 1.42, as opposed to 1.33 used in the application calculations.

12. Overview of the proposal: Strengths & weaknesses

Strengths: Tanzania has a record of good vaccine coverage and should be able to implement this vaccination with adequate coverage and in the timelines indicated, provided the budget allows training and IEC materials to be developed and implemented in sufficient time. The cold chain capacity is adequate.

Weaknesses: Costings in the proposal require clarification, since it is not evident what the shortfall for introduction activities will be. There is no information on ongoing SIAs for measles in the Introduction Plan and the cMYP indicates the current measles campaign is to be completed in 2014, with no information if further SIAs will be conducted after 2014. There are inconsistencies in the vaccine wastage factor used in application and Introduction Plan, and explanations for using a vaccine wastage figure lower than the maximum were not provided.

Risks: If the budget shortfall for introduction is the higher figure, no details have been given on how this will be met. It is unclear if measles SIAs are to be discontinued after 2014 and, since addition of MSD covers only a single birth cohort and it takes time to achieve high coverage, countries should not interrupt regular SIAs.

Mitigants: If the budget shortfall is more substantial than indicated in some of the costing data, then the programme may be unable to undertake all activities for vaccine introduction. SIAs should only be discontinued when WHO criteria have been met.

13. Recommendations

Vaccine: Measles second dose
Recommendation: Approval with clarifications

Clarifications:

1. Please clarify the total and yearly budgets for both vaccine introductions and vaccines/consumables;
2. Please clarify the timelines for MSD introduction;
3. Provide country planning information for measles SIAs post-2014. Measles SIAs should only be discontinued when WHO criteria for stopping follow-up SIAs has been met; and
4. Reconcile the discrepancies in the estimated vaccine wastage factor in the GAVI application form and the MSD VIP and provide justification for the selected vaccine wastage factor.

Appendix D

GAVI Alliance Terms and Conditions

Countries will be expected to sign and agree to the following GAVI Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between GAVI and the country:

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all funding provided by the GAVI Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the GAVI Alliance. All funding decisions for this application are made at the discretion of the GAVI Alliance Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL

The Country will notify the GAVI Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The GAVI Alliance will document any change approved by the GAVI Alliance, and this application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to the GAVI Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the GAVI Alliance, within sixty (60) days after the Country receives the GAVI Alliance's request for a reimbursement and be paid to the account or accounts as directed by the GAVI Alliance.

SUSPENSION/ TERMINATION

The GAVI Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any GAVI Alliance-approved amendment to this application. The GAVI Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of GAVI Alliance funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the GAVI Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with the GAVI Alliance, as requested. The GAVI Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how GAVI Alliance funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARENCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

ARBITRATION

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US \$100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.

USE OF COMMERCIAL BANK ACCOUNTS

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.