*Reference: 2015 - 015*

04 February 2015

The Minister of Health
Ministry of Health
Rua 1° Congresso No 67 MINSA
Luanda
Angola

**Angola's Proposal to Gavi, the Vaccine Alliance**

I wish to refer to GAVI's information letter dated 12 December 2014 following the review of Angola's proposal for Inactivated Polio Vaccine (IPV) in November 2014 by the Independent Review Committee (IRC) and pleased to inform you that your response to the requested clarification has been deemed satisfactory hence; your request for IPV support has been approved.

In November 2014, WHO revised its guidance on the application of the WHO Multi-Dose Vial Policy for IPV. This revision means that indicative wastage rates are reduced from 50% to 20% for the 10-dose vial and 30% to 15% for the 5-dose vial. The change in the guidance will apply from May 2015 once the manufacturers have moved the Vaccine Vial Monitor (VVM) from the cap to the label.

As Angola is expected to receive its first shipment of vaccine with the VVM on the cap, please note that the higher indicative wastage rate has been applied to calculate the approved doses in 2015, with the lower indicative wastage rate to be applied from 2016 onwards.

Should you require any explanation or further information, please do not hesitate to contact the new Senior Country Manager for Angola (replacing Véronique maeva Fages), Dr Thierry Vincent at tvincent@gavi.org.

Yours faithfully,

Hind A. Khatib

Hind Khatib-Othman
Managing Director, Country Programmes

Attachments: Decision Letter
IRC report

Copy: The Minister of Finance
Director Planning Unit, MoH
The EPI Manager
WHO Country Representative
UNICEF Country Representative
Regional Working Group
WHO Head Quarters, Geneva
UNICEF Supply Division, Copenhagen

**Annex A**

**ANGOLA**

**SUPPORT FOR INACTIVATED POLIO VACCINE (IPV)**

**This Decision Letter sets out the Terms of a Programme**

1. **Country: Angola**
2. **Grant Number: 1518-AGO-25c-X / 15-AGO-08h-Y**
3. **Date of Decision Letter: 04 February 2015**
4. **Date of the Partnership Framework Agreement: 04 October 2013**
5. **Programme Title: New Vaccine Support (NVS)**
6. **Vaccine type: Inactivated Polio Vaccine (IPV), Routine**
7. **Requested product presentation and formulation of vaccine[1]: Inactivated Polio Vaccine, 10 doses per vial, liquid**
8. **Programme Duration[2]: 2015 - 2018**
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

*Please note that endorsed or approved amounts for 2018 will be communicated in due course, taking into account updated information on country requirements and following Gavi's review and approval processes.*

| | 2015 | 2016 | 2017 | Total[3] |
|---|---|---|---|---|
| **Programme Budget (US$)** | **US$1,783,000** | **US$1,291,000** | **US$1,257,000** | **US$4,331,000** |

10. **Vaccine Introduction Grant: US$785,500**

[1] Please refer to section 17 for additional information on IPV presentation.
[2] This is the entire duration of the programme.
[3] This is the total amount endorsed by Gavi for 2015 to 2017.

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**11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):**[4]
The Annual Amount for 2015 has been amended.

| Type of supplies to be purchased with Gavi funds in each year | 2015 | 2016 |
|---|---|---|
| Number of IPV vaccines doses | 1,554,500 | 1,113,200 |
| Number of AD syringes | 1,026,000 | 991,900 |
| Number of re-constitution syringes | 0 | 0 |
| Number of safety boxes | 11,300 | 10,925 |
| Annual Amounts (US$) | US$1,783,000 | US$1,291,000 |

**12. Procurement agency: UNICEF**

**Co-financing obligations:** Gavi's usual co-financing requirements do not apply to IPV. However, Angola is encouraged to contribute to vaccine and/or supply costs for IPV.

**13. Operational support for campaigns: Not Applicable**

**14. The Country shall submit the following documents by the specified due dates as part of the conditions to the approval and disbursements of future Annual Amounts:**

| Reports and other required documents | Due dates |
|---|---|
| 2015 Annual Progress Report or equivalent | 15 May 2016 |

**15. Financial Clarifications:**
**The country has already provided satisfactory response to all requested clarifications.**

**16. Other conditions:**

- If Angola envisages a switch in product presentation, it is encouraged to incorporate elements for both IPV presentations in your initial introduction preparations, in order to minimise the need for later interventions and facilitate the switch. In those circumstances, in principle, no product switch grant will be provided to the country.
- Please send a copy of insurance policy certifying that vaccines and devices are insured as stipulated and required by the Partnership Framework Agreement.
- Please send an updated budget and timelines for the VIG budget. Disbursement will take place upon final approval of the budget and revised timelines.

Signed by
On behalf of Gavi, the Vaccine Alliance

Hind Khatib-Othman
Managing Director, Country Programmes
04 February 2015

[4] This is the amount that Gavi has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.

**Independent Review Committee (IRC) Country Report**
**Gavi Secretariat, Geneva • 10 - 24 November 2014**
**Country: Angola**

## 1. Type of support requested: IPV

| Planned start date *(Month, Year)* | Duration of support | Vaccine presentation(s) *(1st, 2nd, and 3rd choice)* |
|---|---|---|
| April 2015 | 2015 - 2018 | 10 dose, 5 dose, 1 dose |

## 2. In-country governance mechanisms (ICC/HSCC)and participatory proposal development process

Angola is planning to introduce IPV nationwide, starting in April 2015. The Ministry of Health and relevant agencies (WHO, UNICEF) participated in the discussions on introduction of IPV. The IPV introduction was discussed and endorsed by the ICC members in September 2014. CSOs are represented on the ICC. The application was endorsed by the Minister of Health and the Minister of Finance. The country does not have an NITAG.

## 3. Situation analysis – Status of the National Immunisation Programme

Angola has 1,004,075 surviving infants, according to country estimates. It is a Gavi graduating country, starting in the 2016. The country utilized previous Gavi support for strengthening immunization services including introduction of new vaccines.

Administrative estimates suggest that DPT3 coverage has more than doubled from 44% in 2006 to about 90% for the last 4 years. WHO and UNICEF have agreed with this estimate although:

- The WUENIC report does not show any survey results to substantiate it since a MICS in 2001 (at which time the coverage was very low). WUENIC has yet to receive a report from a coverage survey performed in June 2014, after being validated by the country.
- The 2013 administrative estimate of DPT1 coverage is 112%; and
- A UNICEF survey in 2008/2009 (not recognized by WUENIC) found DPT3 coverage of 64%.

The organization that supports DHS surveys (ICF International) conducted a large Malaria Indicator Survey in 2011 but, unfortunately, no questions were asked about immunization coverage.

The proposal acknowledges data quality problems with low completeness and timeliness of routine reports and an unreliable estimate of national population. The number of surviving infants (the denominator) is estimated from projections of the 1970 census. This probably explains why some targets and administrative estimates of coverage exceed 100%. A national population census was completed in May 2014 and results will be available in December 2014.

Angola has introduced three new vaccines, Pentavalent in 2006, PCV in 2013, and Rotavirus in 2014. Angola does not have an active HSS grant. An external EPI review in July 2014 noted staff shortages at all levels, insufficient funding for mobile services, inadequate supervision, problems with data quality and data management and problems with the cold chain and vaccine stock management.

Gavi conducted a graduation assessment in the country in October 2014.The government has funded all traditional vaccines since 2007, and is co-financing pentavalent, Rotavirus and PCV vaccines. The government has no plans for IPV co-financing. The country is currently in default for 2012 and 2013 PCV co-financing payments. This proposal mentions some financial sustainability strategies such as voluntary contribution/taxes. The government has expressed a commitment to fund the new vaccines after graduation.

Angola believed that it had stopped polio transmission and had seen its last confirmed wild poliovirus case in July 2011. Then in October 2013 a case of a VDPV was reported from Huila. The country is among the 10 countries identified by the 'Outbreak Risk Mitigation' task team in May 2014 for polio outbreak risk.

## 4. Overview of national health documents

The current cMYP of EPI covers the period 2011-2015. The IPV introduction is not included in the cMYP, which is soon to be updated.

## 5. Gender and Equity

G.I.I. – N.A.; MMR = 450/100,000. Sex-disaggregated data on immunization is not routinely collected in the country. A survey conducted in 2008/2009 (supported by UNICEF; with a report available from the MICS website) found no significant difference in coverage between boys (36.8%) and girls (38.4%).

This same survey found major disparities in coverage by wealth quintile (17.7% for the poorest quintile vs 64.4% for the wealthiest quintile) as well as by urban (53.4%) vs rural (19.1%). However, administrative estimates suggest that DPT3 coverage has risen 46 percentage points in the last 5 years. Hence, it is quite unclear what disparities persist.

The eastern and southern part are sparsely populated and hard to reach, however there is no specific mention of marginalized or hard-to-reach populations or strategies tailored to reach them. One analysis concluded that 80% of all unvaccinated children in 2012 were concentrated in 25 districts of 6 provinces. The R.E.D. strategy was introduced in 2003, and, if implemented effectively, may address some of the equity issues.

## 6. Proposed activities, budgets, financial planning and financial sustainability

The total operational costs for IPV introduction is estimated at USD 2,141,932. The country is requesting VIG in an amount of US$ 785,500 (37%). Partners (UNICEF and WHO) will contribute 23% and the government will cover the remaining 40%.

The country has asked to receive the VIG directly. All previous VIGs have been given directly to the Ministry of Health and the country is requesting the same for the IPV VIG. No FMA has been conducted; the Gavi secretariat will liaise with the country to finalize the fiduciary arrangements.

The major line items in the VIG are capacity building (51%), micro-planning (25%) and cold chain (17%) and communication and social mobilization activities (3%). Funds were earmarked for the PIE. The proposal presents a logical flow of activities and the unit costs in the budget appear reasonable apart from those for the cold chain (see below).

## 7. Specific comments related to requested support

**New vaccine introduction plan**

The New Vaccine Introduction Plan for IPV clearly outlines the justification for the introduction of one dose of IPV into the routine immunisation programme.

Angola is planning for a nationwide IPV introduction in April 2015. In line with WHO/SAGE recommendations, the IPV will be administered to children at the age of 4 months (16 weeks) jointly with the 2nd dose of OPV, Pentavalent, PCV13 and Rotavirus with no disruption of the usual immunization schedule. The injection site will be the right thigh (3 cm apart from PCV13 injection). The ten-dose presentation of IPV is requested which seems suitable for the country situation (cold chain capacity).

The country allows expedited national registration of WHO prequalified vaccines. The IPV will be delivered through UNICEF SD along with the other routine vaccines.

The activity plan is comprehensive. Activities follow a logical timeline, except perhaps for the training activities (see below).

**Vaccine management and cold chain capacity**

An EVMA was conducted in June 2014. Most of 2011 EVMA recommendations have been implemented but still, the vaccine supply chain system is weak. The main conclusions of the EVMA include no continuous temperature registering; shortage of vaccine storage capacity at all level and in most facilities; no maintenance plan; very weak stock management except at central level, and low vaccine wastage monitoring.

There are newly built walk-in cold rooms at central and province level, but there are still vaccine storage shortages at district and facility level. Some Cold Chain (CC) equipment (incl. solar CC and walk-in cold rooms WICR) is planned to be procured through the IPV VIG and decentralized budgets but it is not likely that they will be installed before IPV introduction in April 2015. The capability of the decentralized system to procure prequalified cold chain equipment in a timely manner is not ascertained. Furthermore, there is no clear description of what cold chain equipment needs to be procured for health facilities level.

The Introduction plan mentions a total budget for cold chain equipment of USD 233,386, with Gavi to provide to provide USD 123,472, Government and partners contributing to the remaining amount. There is no breakdown in the V.I.G. budget line item for CC equipment.

In summary, the EVMA shows major weaknesses in the immunization logistics systems. The findings from the EVMA and the information provided in the proposal raise concerns about the capacity of the country to ensure, before IPV introduction, vaccine storage conditions that are both quantitatively and qualitatively adequate (especially at the service level).

**Waste management**

The National Immunization Safety Plan proposes the gradual purchasing of incinerators. This activity is to be carried out jointly with the Ministry of the Environment. These activities are not budgeted for in the introduction plan.

**Training, Community Sensitisation & Mobilisation Plans**

The IPV technical working group will oversee preparation of revised guidelines and materials. The training methodology was not described in the plan

Angola has a strategic plan for communication and social mobilization for 2011-2015. There are plans to prepare an Advocacy Plan for IPV, which will include resource mobilization, and will involve all key decision-makers including local/community leaders and religious leaders.

The proposal notes that currently there is no significant hesitancy about vaccination in Angola. A communication strategy is also to be developed. A quick qualitative study is planned for this year with UNICEF/WHO support to identify barriers to immunization and inform the communication strategy.

Health workers will be trained on risk communication and on interpersonal communication to reassure parents about the benefit and safety of IPV. To mitigate the concerns of health workers over giving multiple injections at one time, a quick formative research study will be undertaken to understand the perception of both health workers and caregivers about multiple injections.

**Monitoring and evaluation plans**

IPV introduction will be monitored through existing systems. Monitoring tools will be updated to include IPV. Coverage, dropout, wastage rate and AEFIs will be monitored. A PIE is planned six months after the introduction.

A data quality self-assessment survey is planned for selected areas to validate the administratively reported data and the consistency in reporting across different levels. In order to improve the reliability of data and facilitate recovery of vaccination defaulters and to obtain gender information, the country is considering the introduction of a logbook for registering immunized of children.

The proposal speaks of plans to strengthen supervision although the source of funding for this is unclear.

According to the introduction plan, AEFIs are already included in the national list of mandatory notifiable diseases and events. It is planned to formulate a committee to follow up the AEFI cases and reporting. Further training will be done on AEFI surveillance and AEFI registration forms and investigation guides will be updated.

## 8. Country document quality, completeness, consistency and data accuracy

There was relatively good consistency between the different documents of the proposal with the exception of the above mentioned presentation preference. The introduction plan is comprehensive. As discussed there are concerns about data quality. A recent coverage survey and the national population census will hopefully clarify both the size of the population and the true coverage and permit reliable decisions to be made about how much IPV vaccine to supply to Angola.

## 9. Overview of the proposal

**Strengths:**
- Successful introduction of three new vaccines in recent years
- EVMA, EPI review and DQAs in 2014 to help to identify priorities.

**Weaknesses:**
- There is considerable uncertainty about the number of surviving infants.
- WUENIC estimates agree with administrative estimates that DPT3 coverage is 93% (80% for OPV3). However, there still remains considerable uncertainty about coverage. The 2013 administrative estimate of DPT1 coverage was 112%.
- The R.E.D. strategy, if implemented effectively, could address low coverage areas but such a strategy is not discussed in the IPV introduction plan
- The EVMA showed major weaknesses in the immunization logistics systems and insufficient cold chain storage capacity at municipality and health facility levels.

**Risks:**
- Cold storage and vaccine management may be inadequate for IPV introduction
- IPV may be supplied in insufficient quantities due to unreliable population estimates
- Possible inadequate coverage with IPV and issues with accurately ascertaining these coverage levels

**Mitigating strategies:**
- Graduation assessment identified the main gap areas including: strengthening the capacity of the human resources to improve quality of immunization services, data quality, financing, cold chain and supply management, procurement and NRA. The graduation grant should assist with addressing these critical areas.
- Reassessment of the number of surviving infants and reassessment of coverage based recently collected data (census; coverage survey)

## 10. Conclusions

The Republic of Angola has requested support to introduce IPV into their routine immunization system in-line WHO SAGE recommendations. Despite the well written introduction plan, the country faces many programmatic challenges including widespread vaccine stock control problems, insufficient cold chain capacity at lower levels, insufficient numbers of fixed vaccination posts in rural and suburban areas, data quality problems and the unreliable population estimates nationally. The country has experience with previous vaccine introductions and is planning to address these issues.

## 11. Recommendations

**Approval with recommendations**

**Recommendations to the Country:**
1. The IRC strongly recommends that the country delay the IPV introduction date to the second half of 2015, due to issues with the current procurement system in the country and to allow sufficient time to address the cold chain storage capacity gaps at the lower levels (these are gaps typically require 4-6 months to address).

2. Vaccine stock management issues must be addressed to ensure availability of quality vaccines and adequate immunization services at the service level.
3. Work towards establishing a NITAG to assist with the strategic decision-making process for the introduction of new vaccines.
4. To ensure financial sustainability after graduation, it is strongly recommended that the country continue to leverage Gavi vaccine prices and UNICEF procurement mechanisms. Not using UNICEF procurement would dramatically increase the overall costs from an estimated US$25 million for all antigens to US$100 million.
5. A high quality household survey (e.g. MICS, DHS) in the next couple of years is strongly recommended.

**Recommendations to the Gavi Secretariat and Partners:**

1. Main concerns relate to the capacity of the country to ensure both quantitative and qualitative storage conditions at the service level before IPV introduction. The secretariat and partners should follow up with the country on the cold chain storage capacity status before IPV introduction. Technical assistance may be needed to ensure that the cold chain is ready to receive IPV.
2. Gavi and partners should closely follow IPV vaccine stocks to avoid stock outs at the national level.
3. Follow up on the implementation of EPI review recommendations.