Appendix B

Korea DPR

SUPPORT for INACTIVATED POLIO VACCINE (IPV)

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

1. **Country: Korea DPR**
2. **Grant Number:** 1518-PRK-25c-X / 15-PRK-08h-Y
3. **Date of Decision Letter:** 30 July 2014
4. **Date of the Partnership Framework Agreement:** 07 June 2013
5. **Programme Title:** NVS, IPV Routine
6. **Vaccine type:** Inactivated Polio Vaccine (IPV)
7. **Requested product presentation and formulation of vaccine**[1]**:** Inactivated Polio Vaccine, 10 dose(s) 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 2017 and 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	Total[3]
Programme Budget (US$)	US$730,500	US$828,500	US$1,559,000

10. **Vaccine Introduction Grant:** US$289,000

[1] Please refer to section 18 for additional on IPV presentation.
[2] This is the entire duration of the programme.
[3] This is the total amount endorsed by GAVI for 2015 to 2016.

11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):[4]

Type of supplies to be purchased with GAVI funds in each year	2015
Number of IPV vaccines doses	637,000
Number of AD syringes	420,400
Number of re-constitution syringes	
Number of safety boxes	4,625
Annual Amounts (US$)	US$730,500

12. Procurement agency: UNICEF

13. Self-procurement: Not Applicable

14. Co-financing obligations: N/A

GAVI's usual co-financing requirements do not apply to IPV. However, Korea DPR is encouraged to contribute to vaccine and/or supply costs for IPV.

15. Operational support for campaigns: N/A

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

Reports, documents and other deliverables	Due dates
Annual Progress Report or equivalent	To be agreed with GAVI Secretariat

17. Financial Clarifications: Not Applicable

***18.* Other conditions:** Not applicable

If Korea DPR 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 Korea DPR.

Signed by,

Hind H. Khatib

On behalf of the GAVI Alliance
Hind Khatib-Othman
Managing Director, Country Programmes
30 July 2014

[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 • 23 June – 4 July 2014
Country: DPRK

1. Type of support requested: IPV

Planned start date *(Month, Year)*	Duration of support	Vaccine presentation(s) *(1st, 2nd, and 3rd choice)*
Awaiting country clarification (original Oct 2014)	2015-2018	1 dose/vial
		2 dose/vial
		5 dose/vial

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

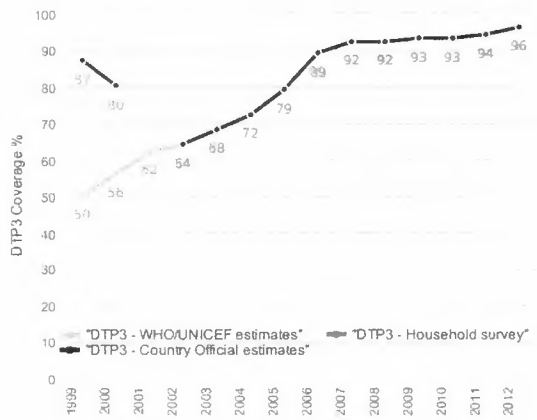
The GAVI application for IPV support was compiled by individuals from the WHO and UNICEF country offices in consultation with the IPV Introduction Task Force. Signatures from both the Minister of Health and the Minister of Finance endorsing the IPV application were provided.

Introduction of one dose of IPV in routine immunisation was presented at an ICC/HSCC held on March 11, 2014, and the application for GAVI support was fully endorsed at a subsequent meeting held on April 17, 2014. During the initial meeting, the ICC/HSCC recommended the immediate formation of the IPV Implementation Taskforce with the responsibility to develop and operationalise the introduction plan and oversee its implementation. The taskforce was formed on March 15, 2014 with representation from Ministry of Public Health, Central Hygiene and Anti-Epidemic Institute, Vaccine Management Unit of Central Medical Warehouse, WHO and UNICEF.

Minutes from the ICC meetings reveal satisfactory attendance of relevant ministers, government officials, representatives from WHO and UNICEF, and CSOs (Korean Medical Association, Korea Children's Health Fund). At the current time, DPRK does not have a NITAG.

3. Situation analysis – Status of the National Immunisation Programme

DPRK has a high-performing national immunisation program. There has been steady improvement in immunisation coverage since 2003, with DTP3 coverage steadily increasing to >95% in 2012 and no districts reporting DTP3 coverage less than 80%. There are no significant differences between country and WUENIC estimates of immunisation coverage; however there has not been a recent coverage survey in the country. The application notes that a coverage survey is planned for mid-2014.



Presently the routine immunisation schedule in DPRK provides birth doses of hepatitis-B and BCG vaccines, three doses of Penta and OPV at 6-10-14 weeks, measles vaccine at 9 and 15 months, and TT to pregnant women.

The government in collaboration with UNICEF and other partners conducted a bottleneck analysis of the EPI in September 2013, focused on the geographical disparities in immunisation services noted in past coverage surveys. The overarching areas where barriers were identified included logistics and supply, geographical inaccessibility, human resources, accessibility, and data monitoring, analysis and interpretation. The introduction plan states that measures to overcome these challenges have been planned, though examples of these measures are not provided in the introduction plan.

The country indicated several success factors from the introduction of pentavalent vaccine including: presence of strong National Task Force for vaccine introduction; detailed operational planning with timelines; successful cascade training to all levels, from national to primary health care level, use of multi-pronged communication to sensitise the media and population on introduction of new vaccine; involvement of high-level officials through official launching of the vaccine; and strong partnership and working relations between MOPH, WHO and UNICEF. Little mention is made of any weaknesses or challenges during past introductions.

4. Overview of national health documents

The country has indicated that the cMYP 2016-20 will be revised by June 2015 and IPV will be included in the updated version. A progress report of the EVM, which was conducted in the last 36 months, was included with the application. However, this is the same progress report that was submitted in to GAVI in 2013.

5. Gender and Equity

Population	24 million
MMR	81/100,000
GII	Not ranked
Penta 3 coverage	97.5% (JRF-2012)

In DPR Korea, the immunisation coverage is high. The Public Health Law emphasises commitment to a health care system that gives special priority to the needs of women and children. The social policies are conducive for equity and access to all citizens of the country irrespective of their geographical, social and gender identity.

The National Coverage Survey Report 2009 (UNICEF) disaggregated coverage data by gender. The survey established that 88.4% of males have fully immunised child status, compared to 88.2% of females, which means there is no significant difference in coverage by sex. Ministry of Public Health has also planned a coverage evaluation survey for EPI in mid-2014; during which immunisation data will also be disaggregated in order to monitor trends in sex disaggregated coverage. UNICEF and the MOPH are currently reviewing and revising routine health information forms, with the proposal to introduce sex-disaggregated data in 2014.

Both routine information systems and coverage survey data disaggregates coverage according to geographic location to county level. The JRF report in 2013 reported that 122 counties out of 209 have coverage greater than or equal to 95% for DPT3, and no counties have coverage less than 80%. In view of the high coverage, available disaggregated data on gender and geographical location and no identified disparities found through reliable data sources, nothing is suggested for gender or equity.

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

The country does not plan to co-finance IPV since this is not a mandatory requirement, but has met co-financing obligations for Penta. The GAVI VIG will be accessed through WHO and UNICEF as per the current FMA between GAVI and the DPRK. The VIG has been calculated appropriately as approximately US$ 288,000, inclusive of WHO (7%) and UNICEF (8%) programme support costs. The country plans on contributing US$ 7,000 of its own funds to the operational costs, with WHO and UNICEF contributing the outstanding US$ 116,000. There is a logical flow of activities in the timeline provided and the unit costs in the budget appear reasonable.

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 IPV into the routine immunisation program in DPRK, in line with the Polio Eradication and Endgame Strategic Plan and the recent WHO SAGE position paper. DPR Korea, along with other ten member states of WHO SEARO, was recognised as polio-free as in March 2014. The last case of wild poliovirus in DPR Korea was identified in 1996, and since then the country has maintained certification as polio-free by sustaining high routine OPV coverage and through maintenance of certification level AFP surveillance. The country has taken recommended measures for laboratory containment of WPV and has developed an emergency outbreak preparedness and response plan to deal with any WPV or cVDPV outbreaks.

The country is planning for a nationwide introduction of IPV. The introduction plan indicates October 2014 as the planned start date for IPV; however, given GAVI feedback that the VIG will not be disbursed until September, the country has agreed to postpone the introduction. The new introduction date will be confirmed at the next meeting of the IPV Task Force meeting.

IPV will be provided to children at the age of 14 weeks along with OPV3 and Penta3, in line with the current immunisation schedule and WHO/SAGE recommendations. IPV will be given in the right thigh and Penta-3 will be given in left thigh. The country has estimated wastage rates of 2% for the 1-dose vial and 5% for the 2-dose vial but has not provided data or justification for the use of these wastage rates, which are less than the WHO indicative wastage rates for these presentations. The country has used an estimated coverage of 100% of surviving infants for dose calculations, which is in line with current DTP3 coverage levels.

The National Drug Regulatory Authority in DPR Korea is fully functional. The NDRA accepts all WHO pre-qualified vaccines irrespective of the presentation. Vaccine procurement will be done through UNICEF, following normal custom clearing procedures.

Vaccine management and cold chain capacity

An EVM assessment conducted in 2011 reports that DPRK reporting systems are meticulous, especially stock reporting. The stock and cold chain management is also enhanced by their "just-in-time" delivery of vaccines at the service point level. This is made possible through their very accurate monitoring and reporting of births. The overall results of the assessment were very positive with major advances made in the preceding 3 years, including the rehabilitation and replacement of cold chain equipment, the repair and maintenance of buildings and the acquisition of delivery vehicles at central and provincial levels. GAVI HHS 1 support enabled this process in 208 counties. Electrical power supply at this level is often unreliable however and the report cautions on the need for standby power supplies if vaccine storage quality is to be assured.

An updated improvement plan reports status as of May 2014. 8 of the 23 listed EVM improvement tasks do not indicate completion. Notable omissions are the use of freeze indicators and increased dry storage capacity. There is no DTR recommendation in the improvement plan.

A bottleneck analysis was conducted in 2013 with a specific focus on a low performing and counties in the northeastern part of the country. The findings provide an excellent opportunity for further improving and ensuring high coverage across the country with a particular focus on vulnerable and hard to reach remote areas. The result of the bottleneck analysis is summarised as poor operation of cold chain equipment; lack of cold chain equipment at rural levels; no solar refrigerators, an absence of regular and adequate power supply; lack of transport for vaccine delivery and supervision; lack of cold chain equipment to conduct outreach activities; lack of vaccine storage facility at service delivery levels; lack of IEC materials and its distribution; limited communication tools, lack of communication between different levels; non-availability and use of monitoring check-list; non reliable electricity. A lack of maintenance and poor knowledge of maintenance practices are also flagged. The extent of vulnerable and hard to reach populations is not indicated, nor is the applicability of these findings nationwide. There is reason for concern however.

A HSS2 application (US$ 26.06 million) has been submitted to GAVI and clarifications approved in March 2014. In HSS2 major focus is on providing cold chain at the level of Routine immunisation (Ri) Hospitals, ensuring access through outreach and catch-up immunisation which could be implemented more rapidly. This will build on cold chain rehabilitation work started under the HSS1 grant. The HSS1 grant was for US$ 4.26 million. The strategy is to equip 1 in 4 Ri's with SDD refrigerators and using passive storage to service other locations. This is sound, and indicates strong orientation to cold chain logistics systems optimisation.

DPR Korea has already demonstrated its capacity to scale up nationally cold chain initiatives through installation of cold chain systems across the 208 counties. It is entirely feasible that DPR Korea has the capacity to extend these systems to Ri level. The IRC did voice concerns however on the scale up capacity given the major increase in budget. **This will not be in place for the introduction of IPV however.**

The primary store (CMW) has refrigerated and insulated vehicles available for distribution to Provincial stores. The Provincial stores have insulated vehicles for their distribution to district/county levels. Distribution to county level does not appear to be an issue. The IPV introduction plan is silent on measures to insure quality storage at county level, given the electrical power situation. It is also silent on the major issue of storage at service delivery points and constraints of outreach.

The budget requested from GAVI to support cold chain for DTR introduction and unspecific capacity needs amounts to US$ 30,000 (10% of budget).

Waste management

No revisions in the current practice of burn and bury or incinerate when incineration equipment is available is envisaged.

Training, Community Sensitisation & Mobilisation Plans

Training on IPV introduction will be focused on: importance and role of IPV; vaccine administration; immunisation schedule review; adjustments in recording and reporting formats in relation to IPV; counseling of mothers and caregivers; AEFI detection, response, reporting, prevention and communication; monitoring vaccination coverage; and community communication. Training materials will be prepared by technical experts at the Central

Hygiene and Anti-Epidemic Institute with guidance from National IPV introduction taskforce. A pool of national trainers will be trained first with cascade training at provinces and counties in batches to cover all health facilities. Effectiveness of training will be determined through pre- and post-test assessment evaluation. The national and provincial EPI teams and national IPV Introduction Task Force members will conduct supervisory visits both prior to introduction to sensitise the health care providers and to assess the quality of the trainings provided, and after introduction to monitor implementation and coverage, and provide support for any AEFIs or other issues in the field.

High-level officials in the ministry of public health have been sensitised through sharing of technical materials highlighting the importance of and benefits of IPV introduction and its contribution to the Polio Endgame Strategy. The communication strategy will also generate support for IPV introduction in other relevant ministries, and at the provincial and county levels to ensure full support to IPV introduction at all levels. A national launching ceremony planned prior to introduction will present a good opportunity for advocacy with other ministries and departments and through mass media to general public interest. The launch will be attended by high level officials from different departments, ministries, civil society representatives, developmental partners, local and international NGOs, electronic and print media and general public. Advocacy events will also be done at the provincial, county, and Ri levels.

A communication strategy with key messages will be developed at the community level through wide participation of key stakeholders and partners under guidance of experts from National Health Information Institute. Different modes of communication and various channels will be used to maximise social mobilisation and support for IPV introduction and routine immunisation intensification. The objective is to create awareness among all community tiers and decision makers to ensure active participation and successful introduction of IPV in the country.

Monitoring and evaluation plans

Recording and reporting tools including registers, wall charts and the computerised database will be revised by technical experts from National EPI and the Taskforce to incorporate IPV. However, immunisation cards will not need to be printed since there are blank spaces available for new vaccines. All other monitoring tools will be printed and transported to the field prior to launch of IPV.

The country does indicate plans to conduct a Post Introduction Evaluation, however, no details on the planned evaluation are provided. Funds have been budgeted for the PIE in Annex D.

There is an adequate AEFI surveillance system in DPR Korea, which was revamped in 2012 prior to introduction of pentavalent vaccine; new AEFI surveillance guidelines were adopted, cascade training from National to PHC level was provided on AEFI for health care service providers and health managers, AEFI reporting forms were prepared, printed and distributed. Health workers are required to record and manage all AEFIs and serious AEFIs must be reported immediately to the health managers and to National AEFI Committee, which has the mandate to institute investigation including causality assessment. Training for IPV introduction will include orientation on AEFI and emphasis will be given to management and prevention of AEFI, risk communication strategies, and the reporting and investigation of AEFI.

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

Due to amendments to the budget requested by GAVI there are several inconsistencies in the budget figures throughout the proposal documents. An updated timeline for introduction as a result of feedback from GAVI has not yet been submitted.

9. Overview of the proposal

Strengths:

- Strong national immunisation program with immunisation coverage > 90% and partners working in close collaboration with GAVI and the government
- Country has met standards for certification of polio eradication including strong AFP and environmental surveillance, and has developed a polio outbreak preparedness and response plan
- Formation of an IPV Introduction Taskforce with appropriate membership responsible for the planning and oversight of IPV introduction
- Presence of CSOs on the ICC/HSCC; the IRC commends DPRK for progress in this area
- Excellent performance during HSS1 support to strengthen the supply chain, and good potential to expand on this experience to address weaknesses at service delivery and outreach locations

Weaknesses:

- Launch date for IPV introduction has yet to be confirmed
- Minimal mention of weaknesses or challenges faced during past introductions; focus was on strengths of past introductions
- No data was provided to support use of wastage rates that are lower than WHO indicative rates; GAVI will use indicative wastage rates to calculate vaccine doses for the initial year. If available, DPR Korea should submit data in their annual report to support the use of lower wastage rates for future years, taking into account that WHO recommends that opened vials of this vaccine should be discarded 6 hours after opening or at the end of the immunisation session, whichever comes first.

Risks:

- Uncertain funding for IPV beyond 2018; country is highly dependent on donor funds

Mitigating strategies:

- Government commitment to the EPI and strong support by UNICEF and WHO country offices
- Introduction of 30-DTR's in all vaccine refrigerators and Freeze Tags in all cold boxes and vaccine carriers, coupled with an appropriate data collection and supervision program to respond to alerts.

10. Conclusions

DPR Korea has requested support to introduce one dose of IPV into their routine immunisation system in-line with the GPEI Endgame Strategic Plan and recent WHO Sage recommendations. The country has met all requirements for approval with minor comments as indicated in the recommendations section.

Recommendation:

Approval with Comments

Comments:

1. Confirm launch date for IPV with the GAVI Secretariat as soon as possible so IPV introduction plans can be revised and initiated as appropriate.

2. Consider the use of, and reporting from, 30-DTR continuous temperature monitoring devices in vaccines refrigerators, especially in low performing and counties in the north-eastern part of the country and preferably nationwide before the introduction of IPV.
3. Implement the 2011 EVM recommendation to use WHO/PQS approved electronic freeze indicators in cold boxes and vaccine carriers when transporting freeze sensitive vaccines.
4. Extend the timeline template for IPV introduction to cover a full 2-year period and clearly indicate all activities and milestones, inclusive of vaccine shipments, maintenance actions, etc.