Decision Letter

KENYA
Yellow Fever Diagnostics and Laboratory Consumables Procurement Support

This Decision Letter forms part of the Partnership Framework Agreement (PFA) and together with the PFA sets out the Terms of the Programme. Any term used in this Decision Letter but not defined shall have the meaning given to such term in the PFA. The English language version of this Decision Letter shall prevail in the case of any conflict with terms expressed in other language(s).

1. Country: Kenya
2. Grant number: KEN-YF-DIAG
3. Date of Decision Letter: 22 March 2022
4. Date of the Partnership Framework Agreement (the "PFA"): 25 November 2014
5. Programme Title: Gavi Support for Yellow Fever Diagnostic Capacity
6. Programme description: The Programme offers a procurement mechanism to improve availability of yellow fever diagnostic reagents, test kits, equipment, and laboratory supplies in African countries that are at high risk for Yellow Fever and eligible for Gavi support. The commodities offered under this programme are: • Yellow Fever RT-PCR test kits • Viral RNA extraction kits for use with the yellow fever RT-PCR test kits • PCR consumable supplies • PCR accessories • ELISA reagents, consumables and equipment (washers, readers, biosafety cabinets) • Test kits (PCR, ELISA and/or Rapid Diagnostic Test), consumables and equipment • Personal protective supplies for yellow fever testing • Time-limited equipment installation, training and maintenance services are also offered for ELISA equipment. There is no cash component to the support offered by Gavi under this Programme. For further information about the Programme please refer to: • Gavi Yellow Fever Diagnostics Procurement Support guidelines and application form available by contacting your Gavi country manager or on the Gavi website at: https://www.gavi.org/our-support/guidelines • Country's approved Yellow Fever Diagnostics procurement support application together with the Gavi Independent Review Committee's (IRC's) report on that application and any requests for clarifications from the IRC.

7. Programme Duration: 2020-2022

8. Joint Investment Classification: Gavi – 100% investment; Country – 0% investment

9. Programme Budget (indicative): This is the amount of an estimated budget endorsed by Gavi under the Programme.

Note: The value of the commodities granted to the country includes costs of shipping and delivery, exclusive of taxes and duties, and may be more or less than these endorsed amounts, subject to the terms of the PFA and Gavi's Policies.

	Year: 2020	Year: 2021	Year: 2022	Total
Gavi Programme Budget ($USD)	**$37,570.50**	**$10,224.00**	**$15,794.00**	**$63,588.50**

10. Indicative amounts of Yellow Fever diagnostic reagents, test kits, equipment, and laboratory supplies (i.e., maximum total supplies to be purchased with Gavi funds).

Items eligible to be purchased with Gavi funds under this Programme	Total number approved for 2020	Total number approved for 2021	Total number approved for 2022
Yellow Fever RT-PCR test kits			3
Viral RNA extraction kits			1
PCR consumable supply bundles[1]			1
PCR reusable accessories bundle[2]			1
Reagent bundles[3]	1	1	
Personal Protective Equipment - Laboratory coats	10	10	
Personal Protective Equipment – Gloves	6400	6400	
Personal Protective Equipment - surgical masks	300	300	
Personal Protective Equipment – goggles	3	3	
ELISA Washer[4]	1		

ELISA Reader[4]	1		
Biosafety Cabinet[4]	1		

[1]PCR consumable bundles contain pipette tips, PCR microtubes, PCR optical caps, conic tubes, and biohazard bags.

[2]PCR reusable accessories bundles contain PCR microtube rack, PCR cap installing tool, and a PCR tube cooler rack.

[3] Each reagent bundle will be supplied as three components: 1) Keep cool elements, 2) General cargo elements, and 3) Elements classified as dangerous goods. Each component is an integral part of the reagent bundle and cannot be requested separately.

[4] Includes time-limited equipment installation, training and maintenance services if needed

11. Additional supplies: The quantities of approved supplies are based on the number of samples expected to be tested over a 12-month period based on the needs foreseen at the time of issuance of this Decision Letter. Per recommendation from the Gavi Independent Review Committee, Gavi has approved $118,128 for procurement of six additional allotments of molecular supplies and $53,286 for procurement of six additional allotments of IgM ELISA supplies. Each additional allotment of molecular supplies is sufficient for yellow fever RT-PCR testing of 480 samples and consists of 5 Yellow Fever RT-PCR test kits, two viral RNA extraction kits, and one PCR consumable supply bundle. Each additional allotment of IgM ELISA supplies is sufficient for yellow fever IgM ELISA testing of 900 samples and consists of 3 reagent bundles, 1800 gloves, 100 masks, and two goggles. These shall be made available to all countries receiving Gavi-support for the procurement of yellow fever diagnostics in the event of yellow fever outbreaks during the time period covered by this Decision Letter. If WHO notifies Gavi of a new or expanded lab confirmed Yellow Fever outbreak in Kenya, Kenya will be eligible to request additional funding of $19,688 for procurement of one such additional allotment of molecular supplies as well as additional funding of $8,881 for procurement of one such additional allotment of IgM ELIS supplies beyond the volumes notified in this Decision Letter for supplies expected to be used outside an outbreak setting. While Gavi has approved this additional funding, its availability to Kenya is subject to the approved funding for procurement of outbreak supplies not having been used by other countries facing a WHO declared Yellow Fever outbreak at the date Kenya submits its request for additional outbreak supplies to Gavi. The procurement agency, reporting requirements, and other terms and conditions will be the same for these outbreak related supplies as for non-outbreak related supplies.

12. Procurement agency: UNICEF Supply Division (SD) is the sole procurement agency for the YF Diagnostic procurement support Programme. Gavi shall release the funding approved for the procurement of the supplies by the country to UNICEF SD each year.

13. Reporting Requirements:

The country's national yellow fever laboratory will report information on yellow fever testing activity and performance within the timelines and manner as requested by the WHO yellow fever laboratory network, including the number of samples received and tested, the results of that testing, the timeliness of the overall testing process and the different steps of that process, and problems encountered with performing yellow fever testing. The country's national yellow fever laboratory will also report information on shipment conditions, such as

temperature monitoring results during shipment, as requested by UNICEF SD. To simplify reporting and avoid duplication, Gavi will rely on information from WHO and UNICEF to inform future decisions on whether to renew support for procurement of yellow fever reagents, test kits, and supplies to individual countries.

14. Other conditions: In addition to the terms of the PFA, the following terms and conditions shall apply to the Programme:

The country is reminded that it is responsible for the reception at the port of entry, customs clearance, and provision of a waiver (or in the absence of a waiver, paying) for any taxes or duties for such consignment of Yellow Fever reagents, test kits, equipment, and laboratory consumables. The Government must provide UNICEF SD with confirmation of such waivers or payments of taxes and duties, as well as country specific requirements for importation, prior to UNICEF SD arranging shipping for yellow fever diagnostic test kits, supplies, and equipment. The country is advised to pay special attention to proposed delivery modes and schedules agreed with UNICEF SD, it's designated supplier(s) and local agent(s) when initiating the deployment and commissioning of goods. If the country needs to make unplanned variations to the delivery schedules, such as cases of force majeure, the Government must develop a deviation protocol to document such cases and include any cost implications of such variations. The Government will be responsible for such costs.

Based on information in the country's Yellow Fever Diagnostics procurement support application, Gavi shall indicate to UNICEF SD that the Arbovirus/Viral Haemorrhagic Fever Laboratory, Center for Virus Research, Kenya Medical Research Institute, Off Mbagathi Way, P.O. Box 54628-00200, Nairobi, Kenya is the final destination for shipment of goods unless country identifies a different final destination for shipment of goods, unless the country identifies a different final destination within 75 km of a port of entry within 14 calendar days from the notification of this Decision Letter.

The Kenya Medical Research Institute may request from UNICEF SD IgM ELISA testing supplies as well as molecular testing supplies for training purposes. The laboratory may request up to the allotted amounts of molecular testing supplies authorized for Gavi funding once it has demonstrated full molecular testing capacity to WHO and full logistical capacity to UNICEF, including an ability to have supplies cleared through customs in a timely manner. However, country public health yellow fever reference laboratories should request from UNICEF SD only the amounts of supplies needed for testing the samples they actually receive, up to the allotted amounts authorized for Gavi funding. If fewer supplies than expected are adequate for testing the actual number of samples received, country public health laboratories should not request the full amount of yellow fever diagnostic consumable supplies authorized for Gavi funding from UNICEF SD.

Utilisation of Gavi support stated in this letter will be subject to performance monitoring.

01 April 2022

Signed by,
On behalf Colette Selman
Director Core Countries a.i