Version: July 2019

[South Sudan]
YELLOW FEVER DIAGNOSTICS REQUEST FORM

This template is for countries requesting Gavi support for procurement of yellow fever diagnostic reagents, supplies, and equipment under the Gavi Board-approved Yellow Fever Diagnostics initiative. The following are mandatory requirements to be submitted alongside this request form:

Signatures required to endorse this request before submission to Gavi: i) Minister of Health, ii) Director of national yellow fever laboratory, and iii) Director of Finance for Ministry of Health. The signature of the Minister of Finance (or their delegated authorities) is recommended but not required.

The Coordination Forum (ICC, HSCC or equivalent body) is required to endorse this request before submission to Gavi. This can be done also through the ICC/HSCC endorsement of the Joint Appraisal (JA) and should be reflected in ICC/HSCC minutes.

Yellow fever diagnostic procurement support is provided to allow more timely, reliable identification and laboratory confirmation of yellow fever cases for more rapid containment of outbreaks and better prioritisation of preventive yellow fever vaccination efforts. Specifically, this support is intended to assist countries' efforts to follow World Health Organization (WHO) recommendations when conducting yellow fever diagnostic tests on all samples received from suspected yellow fever cases. The support is only available to Gavi-eligible countries in Africa that are classified as "high-risk" for yellow fever by WHO under the Eliminate Yellow Fever Epidemics (EYE) strategy[1]. The countries that currently meet those criteria are listed in the **Yellow Fever Diagnostics Support Guidelines**.

The request will be reviewed by members of the Independent Review Committee (IRC) who will make a recommendation to Gavi[2]. Following the independent review there will be a clarification period (30 working days) for countries to respond to any 'issues to be addressed' ahead of final Gavi approval and disbursement.

Submit this request form and the aforementioned requirements to: proposals@gavi.org

Countries requesting Gavi support for the introduction of yellow fever vaccine into the routine immunisation schedule or yellow fever preventive mass campaigns should consult the Application guidelines (section 5.3.8) for more information on the process and requirements. Countries requesting Gavi support for rapid outbreak response for yellow fever (via the International Coordinating Group (ICG)), should consult the yellow fever Application guidelines in the ICG site.

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[1] *The list of Gavi-eligible countries is provided in* ***Annex 1 Yellow Fever Diagnostics Guidelines****. For the full list of WHO classification, see 'World Health Organization. Eliminate Yellow Fever Epidemics (EYE): A Global Strategy, 2017-2026. Wkly Epidemiol Rec 2017;92:193-204."*

[2] *The requests for consumable reagents and supplies will be reviewed separately from requests for equipment, so support for requested consumables may be recommended even if support for requested equipment is not recommended.*

Gavi Grant Terms and Conditions

Gavi terms and conditions

The terms and conditions of the Partnership Framework Agreement (PFA) between Gavi and the Country, including those provisions regarding anti-corruption and anti-terrorism and money laundering, remain in full effect and shall apply to any and all Gavi support made pursuant to this application. The terms and conditions below do not supersede those of the PFA. In the event the Country has not yet executed a PFA, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

GAVI GRANT APPLICATION TERMS AND CONDITIONS

SUPPLIES AND EQUIPMENT USED SOLELY FOR APPROVED PROGRAMMES

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

AMENDMENT TO THE APPLICATION

The Country will notify Gavi in its Joint Appraisal, or in any other agreed annual reporting mechanism, if it wishes to propose any change to the programme(s) description in its application. Gavi will document any change approved by Gavi according with its guidelines, and the Country's application will be amended.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, or any other agreed annual reporting mechanism, is accurate and correct and forms legally binding obligations on the Country, under the Country's law, to perform the programme(s) described in its application, as amended, if applicable.

COMPLIANCE WITH GAVI POLICIES

The Country confirms that it is familiar with all Gavi policies, guidelines and processes relevant to the programme(s), including without limitation the Transparency and Accountability Policy (TAP) and complies with the requirements therein. All programme related policies, guidelines and processes are available on Gavi's official website and/or sent to the Country.

ARBITRATION

Any dispute between the Country and Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either Gavi 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 languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by Gavi. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: Gavi 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.

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

REPORTING

The Country's national yellow fever laboratory will report information on yellow fever testing activity and performance as requested by the WHO yellow fever laboratory network in a timely and accurate manner, including on 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. To simplify reporting and avoid duplication, Gavi will be relying on information from WHO to inform future decisions on whether to renew support for procurement of yellow fever reagents, supplies, and equipment to individual countries.

1. Review and update country information

1.1. Country profile

1.1.1. Country profile

Eligibility for Gavi support

The decades of war and a protracted grade 3 crisis have increased the vulnerability of South Sudan to disease outbreaks and emergencies. Physical access to health care is estimated at less than 50%, routine immunisation estimated at 26%, and access to safe water and sanitation estimated at less than 50% and less than 10% respectively. High-threat infectious hazards remain a major threat to public health security in South Sudan. At least two yellow fever outbreaks have been reported in South Sudan with 178 cases and 27 deaths (15%) in Torit and Ikotos counties and in 2018 with three confirmed cases in Sakure, Nzara county. Further, a yellow fever risk assessment undertaken in South Sudan in 2014 showed that Nimule, Torit; Kapoeta and Narus had prevalence of 2-3% natural yellow fever infection. These findings highlight the risk of yellow fever infection and the need to strengthen surveillance and the initiation of preventive yellow fever vaccination to protect at-risk populations.

Date of Partnership Framework Agreement with Gavi

Enter date

1.1.2. National customs regulations

Please describe local customs regulations that are instrumental for the delivery of imported laboratory supplies and equipment.

All donations to government should be issued with a tax exemption note by Government based on a zero-cost invoice. It's on this basis that a greenlight is issued for shipment of donations line laboratory supplies and equipment to proceed.

Donations

a) Donations must be in accordance with the *Guidelines for Donation of Medicines, Medical Supplies and Equipment in Southern Sudan 2007*(refer to this for details)
b) Companies or Organizations intending to import pharmaceuticals for donations will still be required to apply for an Import License and go through a formal verification process of the application (see below)
c) Donors must attach a list detailing the intended recipients and where they are located in South Sudan
d) Waivers on some of the requirements in these guidelines may be granted on a case by case basis

Please describe requirements for pre-delivery inspection of imported goods that are instrumental for the delivery of laboratory supplies and equipment.

Please describe any special documentation requirements that are instrumental for the delivery of imported laboratory supplies and equipment.

The **South Sudan Drug and Food Control Authority act** stipulates that all importation of pharmaceutical products must be done by pharmaceutical companies who are duly licensed and

registered with the **Drug and Food Control Authority, Republic of South Sudan.** All medicinal products imported into South Sudan must be entered into a database maintained by the Department of **Marketing Authority, Secretariat Drug and Food Control Authority, Republic of South Sudan (SDFCA/RSS).**

Therefore, all pharmaceutical importers (commercial or donations) must make available to the **Secretariat**, at the minimum, the following pre-shipment information, before any consignment of pharmaceuticals arrives in South Sudan from any part of the world:

a) Name of the medicinal product (*INN/generic and brand name where applicable*)
b) Pharmaceutical form (tablets, capsules, injectables etc), strength and pack size
c) Pharmacopeial specifications (*BP, IP, BPC, USP, etc*)
d) Composition (active substance(s) and, if appropriate, excipients)
e) Manufacturer's name, and address
f) Marketing authorization holder and authorization number in the country of origin
g) Supplier in the country of origin (*if different from manufacturer*)
h) Quantity being imported
i) Batch/lot number
j) Manufacture and expiry dates (*Minimum remaining shelf-life of two years or at least 2/3 stated shelf-life*)
k) Mode of transport
l) Port of entry
m) Expected date of arrival
n) Address of warehouse or health facility where the pharmaceutical products will be kept

1.1.3. National Regulatory Agency

Please provide information on the National Regulatory Agency in the country, including status (e.g., whether it is WHO-certified).

National Drug Food and Control Agency regulates the importation of medicines; vaccines; and medical supplies.

Please identify at least one point of contact with phone number and e-mail address at the National Regulatory Agency. UNICEF will help work with regulatory processes where relevant and may need to communicate licensing requirements to laboratory supply manufacturers.

Dr. Peter Aguek kon Baak
Director General for Inspection and Surveillance
Department of Licensing and Registration,
Secretariat of Drug and Food Control Authority,
Republic of South Sudan,
Ministry Complex, Juba, South Sudan

2. Yellow fever laboratory supplies and equipment

2.1. Number of samples from suspected yellow fever cases expected to be tested for which supplies will be needed

Number of samples received for testing in 2016	129
- Yellow fever outbreak in 2016?	Yes ☒ No ☐
Number of samples received for testing in 2017	16
- Yellow fever outbreak in 2017?	Yes ☒ No ☐
Number of samples received for testing in 2018	56
- Yellow fever outbreak in 2018?	Yes ☒ No ☐
Number of samples expected to undergo ELISA testing over a 12-month period[3]	50
Number of samples received for testing in 2016 that were collected ≤10 days after onset of illness	50
Number of samples received for testing in 2017 that were collected ≤10 days after onset of illness	9
Number of samples received for testing in 2018 that were collected ≤10 days after onset of illness	24
Currently testing for yellow fever with polymerase chain reaction (PCR)?	Yes ☒ No ☐
- If yes, what type of PCR machine is used?	ABI PCR
- If no, please describe any plans for starting testing for yellow with PCR in the next 12 months, including description of PCR testing already being done for other viruses	
~~Number of samples expected~~ to undergo PCR testing over a 12-month period[4]	

[3] Number of samples expected to undergo ELISA testing over a 12-month period may be estimated to be equivalent to the largest number of samples received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples were received for testing in 2017 than in 2016 or 2018, the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2017. If an outbreak occurred in 2017 and more samples were received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2018. Alternative approaches can be used if justification is provided.

2.2. Equipment

Does your laboratory receive at least 50 samples a year for yellow fever testing and need an enzyme-linked immunosorbent assay (**ELISA**) **reader** for yellow fever testing? Yes ☒ No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.

  From the 2018 – Laboratory assessment report; 38 samples were collected in 2015; 129 samples in 2016; 16 samples in 2017; and 56 in 2018 for yellow fever testing.

- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.

  We already have a PCR ABI machine for arboviral testing and influenza testing and we have an ELISA reader for measles testing.

Does your laboratory receive at least 50 samples a year for yellow fever testing and need an **ELISA washer** for yellow fever testing? Yes ☒ No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.

  The National Public Health Laboratory has an ELISA reader but the WASHER needs to be replaced as its currently washed manually.

- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.

  ELISA reader is currently used for measles testing in the National Public Health Laboratory. There are staff trained in measles/rubella testing. In addition; this year the team underwent training in Yellow Fever PCR testing.

Does your laboratory receive at least 50 samples a year for yellow fever testing collected no more than 10 days after patients' onset of Yes ☒ No ☐

50 samples

[4] *If capacity to test for yellow fever with PCR is available, the number of samples expected to undergo PCR testing over a 12-month period may be estimated to be equivalent to the largest number of samples collected ≤10 days after onset of illness and received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples collected ≤10 days after onset of illness were received for testing in 2017 than in 2016 or 2018, the number of tests expected to be run over a 12-month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2017. If an outbreak occurred in 2017 and more samples collected ≤10 days after onset of illness were received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12 month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2018. Alternative approaches can be used if justification is provided.*

illness and need a **PCR machine** for yellow fever testing?

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.

There is an installed ABI PCR machine that is current installed and used for arboviral and influenza testing. The staff have been duly trained to undertake the testing

- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.

ELISA reader is currently used for measles testing in the National Public Health Laboratory. There are staff trained in measles/rubella testing. In addition; this year the team underwent training in Yellow Fever PCR testing.

Does your laboratory need a **biosafety cabinet**? Yes ☒ No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.

There is are BSCII cabinets for sample processing

- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.

The ELISA Plate Washer is down and not yet repaired

2.3. Logistics

2.3.1. Supply delivery

What is the address and, if available, geocoordinates of the national public health yellow fever reference laboratory that is the ultimate destination for yellow fever laboratory supplies and equipment?

The National Public Health Laboratory in Juba; South Sudan

What is the Port of Entry closest to the national public health yellow fever reference laboratory?

Juba International Airport

How many shipments should the needed supplies be spread across and why?[5]

At least twice a year given the volume of transport and available cold chain storage capacity.

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[5] *Gavi will fund a maximum of three shipments for supplies used in routine yellow fever testing over a 12-month period (additional shipments are possible in response to outbreaks, if feasible). Exact shipment dates, times, and other details to be confirmed with UNICEF Supply Division.*

To facilitate timely delivery of supplies, laboratory staff will be responsible providing proof of customs clearance and other import authorizations prior to scheduling a shipment with UNICEF Supply Division. What is the laboratory's plan for securing the necessary customs clearance and any other import authorizations?

Provided the invoice and shipment documents are shared well in advance; the laboratory will facilitate the process of securing tax exemption certificate from Government.

2.3.2. Logistical technical assistance

Does the laboratory staff need stock management training? If yes, please provide details

- The 2018 Gavi assessment showed that there is NO Reagent inventory management in laboratory MS Excel
- There is therefore need for stock management training of the laboratory team.

2.4. Strategic considerations

2.4.1. Rationale for the request

Briefly describe how yellow fever diagnostic capacity fits into your country's plan for eliminating yellow fever epidemics.

The country has developed the EYE strategy in which enhanced yellow fever surveillance including capacities for yellow fever screening and confirmatory testing are core targets of the strategy.

2.4.2. Financial sustainability and budgeting of yellow fever laboratory

A cost sharing requirement will eventually be introduced for **yellow fever materials. This cost-sharing will not come into effect through at least the end of 2020. More information will be provided by your Gavi Senior Country Manager (SCM) as it becomes available. **

What is the current year's and, if available, the next year's domestic budget for yellow fever laboratory capacity needs, including yellow fever laboratory supplies and equipment?

USD $250,000

2.4.3. Anticipated future changes in yellow fever laboratory capacity

Aside from access to yellow fever diagnostic reagents, supplies, and equipment, does the laboratory expect its capacity to test for yellow fever to change over the next 2 years, e.g., new staff, training, new facility, etc.? If so, how?

The staff undergo regular yellow fever testing training and have just returned from a training in Yaoundé, Cameroon. There is also ongoing mentorship from Uganda Virus Research Institute to support enhancement of yellow fever testing. At least three molecular scientists have been trained to support arboviral and influenza PCR testing.

Contacts

Person(s) who should be contacted in case Gavi needs to ask for more information regarding the application.

Name	Position	Phone Number	Email	Organisation
Dr. Lul Lojok	Director General	+211915883753	drlullojok2004@yahoo.com	MoH

Dr. Losuba Mike	Director	+211924019881	losubamichael@gmail.com	MoH
Mr Ayei James	Lab Manager	+211926144993	jamesayei@gmail.com	MoH
Dr. Rachel Seruyange	WHO EPI Lead	+211921702124	seruyanger@who.int	WHO

Comments

Please provide any comments you have about this application and how to improve it

No additional comments

Government signature form

The Government of South Sudan would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for yellow fever diagnostics (that is, laboratory reagents, supplies and equipment) as outlined in this request form.

The Government of South Sudan commits itself to developing national immunisation services, including laboratory testing that helps guide immunisation services, on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of the Minister of Health, the Director of the national yellow fever laboratory, and the Director of Finance for the Ministry of Health or their delegated authorities.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for procuring yellow fever laboratory reagents, supplies, and equipment will be included in future annual budgets of the Ministry of Health, including funds for co-financing of future Gavi-supported procurement of supplies once the details of the Gavi co-financing requirements are available.

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.[6]

Minister of Health (or delegated authority)	**Director of national yellow fever laboratory (or delegated authority)**
Name: Dr. Riny Nyiuol	Name: James Ayei Maror
Date: 24.01.2020	Date: 24.01.2020
Signature:	Signature: 24/1/2020

Director of Finance for Ministry of Health (or delegated authority)	**Minister of Finance (or delegated authority) (recommended but not required)**
Name: Angelo Goup Thon	Name:
Date: 23/01/2020	Date:
Signature:	Signature:

[6] *In the event the Country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.*