Abbreviated form for the request of additional doses

Below are key features to be included in the request form:

1. The request will be endorsed by an authorised official from Ministry of Health and Ministry of Finance.
2. The completed request must be submitted to Gavi by e-mail (proposals@gavi.org copying the SCM) by **22 January 2018**.

Context

The section briefly captures relevant information on the context rationale including some of the following:

(i) Country context

- *Country situation*
- *Epidemiological context*

(ii) Programme context

a. *What are the objectives, key indicators, and expected outcomes?;*
b. *What are the specific additional target population (specific number of people) to be reached?;*
c. *Specific districts/regions/states to be reached;*
d. *What are the actions to be taken?*
e. *What has changed since the original approval? What are the challenges resulting from these changes? What would be the interventions necessary to address these changes?*
f. If applicable, indicate how these additional doses were provided prior to "this request"" along with the previous source of funding (i.e. other donor, government, etc.)

(iii) How does this request?

(iv) Please discuss if this request would addresses any coverage and equity issues

(v) Brief summary of engagement with other key stakeholders

(Maximum 1000 words)

Country context

The Republic of Kenya is situated in East Africa. It is bordered by Tanzania to the south and southwest, Uganda to the west, South Sudan to the north-west, and Ethiopia to the north and Somalia to the north-east. Kenya covers 581,309 km2 (224,445 sq mi), and had a population of approximately 48 million people in January 2017. The country appreciates the role immunisation plays in improving new born child survival. The 2016 population in Kenya is estimated at 45,367,322 with live births 1,591,167, and surviving infants 1,514,775

Kenyan health sector and immunisation

The health sector in Kenya has recently undergone major changes as a result of the enactment of the new Constitution of 2010. The constitution defines two levels of governance: the national and the county governments. There are 47 semi-autonomous devolved units (the counties) under the constitution, which are headed by governors. The counties are further divided into 299 sub counties, the equivalent of districts under the old constitution. With regards to health, the constitution defines the functions of the national and devolved governments. The national immunization services in the country are managed by the Ministry of Health through the National Vaccines and Immunization Program (NVIP). The program provides policy direction and provides technical support as well as oversees the implementation of immunization services. The program is classified as strategic national programs and report through the respective divisional heads to the Director of Medical services. The county governments MoHs are responsible for the actual health service including provision of immunisation services. The two levels of MoH receive separate budgets to fulfil their mandates. The national MoH is working closely with the county governments to refine and clarifying roles and responsibilities for the two levels of governance.

The NVIP established in the 1980 as Kenya Expanded Program for Immunisation (KEPI) began by providing vaccination targeting six childhood diseases has in place an immunisation multi-year plan (cMYP 2015-2019), which provides the roadmap for achieving the goals and objectives of Kenya Health Sector Strategic and Investment Plan 2014-2018. The cMYP 2015 -2019 is aligned to the objectives global and regional WHO Vaccine Action Plan and the Decade of Vaccines.

Objectives, targets and justification for the Yellow fever (YF) vaccine expansion of routine immunisation.

Objectives for the expansion

Kenya is planning to introduce YF into routine immunization into 2 counties - Turkana and west Pokot targeting approximately **55,737** persons aged 1 year using the Yellow Fever Vaccine in 2018. The YF vaccine will be delivered through the existing National routine immunization system. The strategy for implementation will be through the fixed health facility.

The vaccine will be administered as a single intramuscular dose (0.5 ml), injected intramuscularly in the left deltoid, left upper arm at the same sitting with Measles Rubella Vaccine. The vaccination site is usually the lateral aspect of the upper part of the arm or the anterolateral aspect of the thigh in babies and very young children.

It is hoped that this introduction will create an opportunity to strengthen the acceptance and uptake of yellow fever vaccine in the country. It will additionally strengthen Yellow Fever surveillance and routine immunization programme.

The objectives of the introduction are:

1. To prevent future outbreaks of Yellow Fever in Kenya through expanding the routine immunisation in high risk counties – Turkana and West Pokot.
2. To contribute to the increase in immunity against Yellow Fever in country and globally.

Justification

The recommendation for the introduction of the vaccine through routine immunization in 2 high risk counties - Turkana and West-Pokot, is based on a Yellow Fever risk assessment that was conducted with the support of WHO in Kenya in 2013.

The results of this assessment showed that Kenya is within the low risk category with a national sero prevalence of 0.46%. The highest sero prevalence was in Zone 2 (1.7%) which was still low Only one site in the country (Turkana County) was found to have an abnormally high sero prevalence of 5.5% and therefore of concern to the country.

The sero-prevalence in zone 2 (1.7%) was higher than the National sero-prevalence. When stratified by sites within the zone; Turkana Kakuma had the highest at 5.5%. The high sero-prevalence in Turkana's Kakuma could be due to YF mass vaccination campaign in 2003 following yellow fever outbreak in South Sudan. However, none of the respondents that tested positive reported having been vaccinated during this campaign. Since the vaccination had been done 10 years before the risk assessment, this may have resulted in recall bias. Given that this area borders South Sudan, Ethiopia and Northern Uganda which have had yellow fever outbreaks in the recent years, the high sero-prevalence could be attributed to naturally acquired YF immunity due to exposure.

These results were considered due to Turkanas population movement dynamics. First, Turkana has had constant refugee movement from Uganda and South Sudan (to the Kakuma Refugee Camp) which have had yellow fever outbreaks in the recent years. Second, Turkana residents (pastoralists) also move to Uganda and Sudan in search for pasture during dry seasons and come back during wet seasons hence risk of infection. Third, host community in Turkana interacts with the refugees from South Sudan hence increasing the risk of infection.

Although the assessment demonstrated the presence of Aedes (stegomyia) group of mosquitoes the well-known efficient vectors of urban Yellow Fever in eight of the study sites (2A, 2D, 2E, 3A, 3B, 4A, 4B and 5B), none tested positive for Yellow Fever virus. Even in the absence of YF viral activity in some of the sites the epidemic risk indices (Breteau Index and Container Index) were potentially elevated hence risk of an epidemic if the virus was to be introduced into the population.

West Pokot County is epidemiologically similar to and is nestled/ enveloped by the Counties at high risk of yellow fever- Baringo, Elgeiyo Marakwet and Turkana. The Country therefore plans to include West Pokot.

Integration with ongoing programmmes

The country conducts Yellow fever vaccination routinely in 2 counties Elgeyo Marakwet and Baringo . Kenya will expand and integrate the YF vaccination into 2 new counties- Turkana and West Pokot

using the same existing strategies and systems. However, the training materials will be updated with the new information and guidelines. The ACSM subcommittee will develop an appropriate context specific strategy to reach the communities and generate demand in the 2 new counties as well as take the opportunity to increase YF coverage and acceptance in the country. The measles-rubella second dose will provide an opportunity to reach more children that would have missed earlier on with yellow fever vaccine.

The program will also leverage on this opportunities to increase coverage of other vaccines in the region as well as any challenges identified during and after implementation will be addressed to strengthen the weaknesses in the system as a whole.

Engagement of stakeholders

NVIP recognizes the importance of having various groups in place to oversee the introduction of new vaccines and has put in place steps to adopt a multi-stakeholder approach in the YF introduction. NVIP sought endorsement through KENITAG and the National Immunization Inter-agency Coordination Committee (N-ICC) on the introduction of YF. The role of the N-ICC in conjunction with NVIP will be to oversee pre planning activities, progress and challenges. The role of KENITAG includes providing An advisory opinion on the introduction of any new vaccines to the routine immunization system and to ensure that there are considerations around the impact of YF vaccine on the immunization program and the overall health system.

Secondly, there is a YF technical working group headed by NVIP staff. It includes members from NVIP and partner organizations. The TWG is responsible for deliberating and selecting a delivery model for introduction including conducting a cost benefit analysis of the different delivery models and supporting the Government in all introduction related activities. The TWG will include representatives from different sub-committees who will execute preparations in different areas related to the introduction with focus on the following: Training, Communication and social mobilization, logistics and Monitoring and evaluation.

Past implementation challenges and lessons learned from Gavi/other partner support in your country as applicable. Explain how these challenges and lessons learned are taken into account in this request

(Maximum 800 words)

The country has introduced a number of new vaccines in the recent past: Pentavalent in 2005, PCV in 2011, Rota Virus Vaccine and Measles Vaccine Second Dose in 2014, IPV in 2015 and Measles Rubella Vaccine in 2016. Various PIEs have been conducted contributing to lessons learnt. The last Kenya Effective Vaccine Management Assessment (EVMA) was conducted in November 2013. In addition, the country conducted a HPV demonstration project (2013-2015) to assess coverage, acceptance and affordability/ feasibility.

- The HPV PIE undertaken in July 2014 noted the following
    - Accurate microplanning needed to be done to identify numbers of the target population
    - The importance of timely vaccine supply
    - The importance of
      Appropriate advocacy and social mobilization using the cervical cancer prevention platform
- The MCV2 introduction in 2014 was hampered by inadequate funds leading and this affected the quality of training, health worker knowledge, demand generation and service delivery resulting in a low coverage
- The Rota PIE noted that there was unavailability of technical guidelines at subnational level. It was recommended that new vaccine introductions be supported by appropriate technical guidelines and practical job-aides availed up to the operational level
- The EVMA 2013 identified deficiencies in vaccine management including prolonged clearance time at port of entry, gaps in temperature monitoring, inadequate cold chain capacity and gaps in supportive supervision.
- Following Rota Vaccine introduction, counties reported increased cost of operation, especially costs related to the transportation of vaccines, following RV introduction. The cost associated with this increase in the frequency of vaccine collection was mostly borne by the sub-county level. This is possibly due to inadequate storage/transportation space. Cold chain space was strained at service delivery (health facility) and sub-county stores due to the increased demand imposed by rotavirus vaccines. Kenya conducted an equipment inventory in 2011. This inventory was updated in 2015 and 2016. Between the inventory periods, the number of immunizing health facilities and cold chain equipment has increased. With support from the German government through KFW and UNICEF the national level procured equipment including spare parts and supported training of 47 METS and repairs of non-functional cold chain equipment. Several county governments have also procured EPI fridges. This support contributed to reduction of proportion of non-functional equipment from 840 (17%) in 2011 to 563 (8%) in 2016. The NVIP has developed a 5-year Cold Chain Expansion and Rehabilitation Plan (CCERP) that will guide investment in cold chain. To finance the plan, the MOH will enhance its advocacy activities with county leadership and immunization partners, as well as mobilize resources for CCE through Gavi HSS and CCEOP.
- The MR campaign was postponed due to delays in clearance of vaccine related supplies (safety boxes). It is important to ensure these supplies are cleared in time for the planned exercise
- Collaboration with other ministries e.g. Education led to the success of the MR Campaign
  During the 2016 measles rubella campaign use of SMS mode of communication to clientele resulted in great penetration and demand generation. Going forward, it would definitely be worthwhile and investment to add this form of communication to routine immunization/ vaccine introduction and explore ways of obtaining the service more affordably through our popular mobile service providers.

- Through increased engagement with stakeholders, especially religious leaders and immunization champions, vaccine hesitancy has declined. There is however, still need to map hesitant groups and key stakeholder and to increase engagement with health professionals and civil society to enhance their understanding of the immunization program strategies and challenges.

Since the YF introduction is being implemented in 2 counties, where the target population is not big and the vaccine doses to be requested is not huge. The program does not expect to have any challenges in this expansion. However to foster preparedness- a cold chain assessment will be conducted at implementation levels in order to be able to address any emerging challenges or gaps. The counties are also expected to benefit from the CCEOP project in terms of cold chain expansion. The lessons learnt during planning and implementation of other vaccine introductions will be factored in order to have a successful implementation.

The total co-financing requirement for 2018 amounts to US$ 939,500 broken down in the table below:

Type of supplies to be purchased with Country funds in each year	**Pneumococcal (PCV10), 4 dose(s) per vial, LIQUID, Routine[1]**	**DTP-HepB-Hib, 10 dose(s) per vial, LIQUID, Routine**	**Rotavirus, 2 dose(s) schedule, Routine**	**Yellow Fever, 10 dose(s) per vial, LYOPHILISED, Routine**
Number of vaccine doses	99,600	403,000	147,000	600
Number of AD syringes	67,300	248,700	-	-
Number of re-constitution syringes	-	-	-	100
Number of safety boxes	750	2,750	-	-
Total co-financing payments (US$) (including freight)	**308,500**	**324,500**	**305,500**	**1,000**

Vaccine related specifics:

Year	Vaccine name and presentation	Wastage	Surviving infants	Number of recipients to receive a recommended dose of YF according to coverage target
2018	STAMARIL 10 dose	40%	55,737	(90 *55737) 50,200

Other comments/recommendations (optional)

[1]*The country has requested a switch from PCV10 2ds to PCV10 4ds in 2018. This switch has been approved by Gavi for implementation from 2018 onwards, pending programme approval by the High Level Review Panel and subject to WHO pre-qualification of the PCV10 4ds presentation. The number above indicated the total number of PCV doses for 2018; the final allocation of PCV10 2ds and PCV10 4ds vials will be determined at a later stage, based on your desired timing of the switch, the stock of the existing presentation of PCV, supply availability of the PCV10 4ds vial, and country programmatic readiness to switch. We will aim to provide the first shipment of PCV10 4ds vials 2 months ahead of the stock exhaustion of the doses of your current presentation in 2017 Decision Letter, otherwise we will continue to provide shipments of PCV10 2ds based on the factors mentioned above until the switch takes place.

Provide any additional contextual information relevant to the request (any explanations that further clarify any possible linkages, routine monitoring, any considerations, or data that informed the request or updates of the request)

Government signature form

The Government of (country) 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:

Routine Yellow Fever

The Government of (country) commits itself to developing national 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.

The co-financing commitments in this application include the amount of support in either supplies or cash that is requested from Gavi, and the financial commitment of the Government for the procurement of this new vaccine.

Please note that Gavi will not review this application without the signatures of both the Minister of Health and Minister of Finance or their delegated authority.

Minister of Health (or delegated authority)	**Minister of Finance (or delegated authority)**
Name	Name
Date	Date
Signature	Signature

To support your request, please ensure the following documents are attached to the short form:

- Updated Grant Performance Framework that reflects the new targets;
- Interagency Coordinating Committee (ICC) meeting minutes endorsing the application;
- Joint Appraisal or other situational analysis report;
- Formal risk assessment(s) (in situations where the expansion should be/is based on these assessments); and
- Vaccine introduction plans for additional regions.