

# Nigeria, National Primary Health Care Development Agency



## **One Dose Decision Making in Nigeria** **A Progress Toward Successful HPV Introduction** **and Accelerating Coverage in Nigeria**

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**September 24, 2022**

**NATIONAL PRIMARY HEALTH CARE DEVELOPMENT AGENCY**



01



## Introduction

- NPHCDA's Vision, Mission, Goals and Core Mandates
- Structures for Routine Immunization and Decision Making Process in Nigeria

02 Milestones of other New Vaccine Introductions and HPV Vaccine

03 Factors that influence decision for One Dose HPV vaccine introduction

04 Previous Recommendations and review to One dose decision for HPV Introduction in Nigeria

05 Status of the Country's Submission as at September 2022

06 Challenges and Immediate Next Steps





The NPHCDA is a parastatal under the Federal Ministry of Health with the mandate to provide technical and programmatic support to states and LGAs on the Development of Primary Health Care in Nigeria



## Our Vision

**To make Primary Health Care (PHC) services available to all in Nigeria**

## Our Mission

**To provide leadership that supports the promotion and implementation of high quality and sustainable primary health care for all**

## Our Mandate

- Provide support to the National Health Policy for the development of Primary Health Care
- Establishment of guidelines, protocols and standards for Primary Health Care
- Provide technical support for planning, management and implementation of PHC
- Mobilize resources nationally and internationally for the development of Primary Health Care.
- Provide support for monitoring and evaluation of the National Health Policy.
- Promote health manpower development needs for Primary Health Care through orientation and continuing education.
- Provide support to the Village Health System by training Village Health Workers.
- Promote Health System Research by promoting and supporting problem-oriented health system research
- Promote technical collaboration by stimulating Universities, NGOs and International Agencies.
- Provide annual reports on the status of Primary Health Care implementation nationwide.



# Agency's seven (7) corporate goals



-  **Control Preventable Diseases:**  
Eradicate polio, and limit the occurrence and impact of diseases using education, immunization and other proven interventions
-  **Improve access to Basic Health Services:**  
Make basic health services available by ensuring communities have access to health facilities, services and basic health
-  **Improve quality of care:**  
Ensure basic health services are people-oriented and delivered according to established quality standards and protocols
-  **Strengthen the institution:**  
Strengthen Zonal structures, State representation, internal communications, monitoring and evaluation, procurement and the financial management system
-  **Develop high-performing health workforce:**  
Organize systems and structures to deliver effective support services through, for example, PPHC guidelines, norms and enabling acts for states and LGAs
-  **Strengthen partnerships through the integration of services and commodities:**  
Mobilize and coordinate stakeholders such as Ministries, Departments and Agencies and development partners to strengthen health services delivery
-  **Strengthen community engagement:**  
Promote community participation, ownership and responsibility for health through Ward Development Committees and communication programmes



# The NERICC Mandate, Membership, Vision and the strategic Objectives

## NERICC MANDATE :

Provide a national and sub-national coordination mechanism for full implementation of All strategies towards achieving routine immunization coverage of 90% and above for ALL antigens at national, states and LGAs levels by 2028.

## NERICC Membership

- NPHCDA (Reps from DDCI, PRS, DLHC, Finance, DA, Admin, EOC, DAC etc.)
- WHO
- UNICEF
- CDC/AFENET
- AFENET
- CHAI
- IVAC/DCL
- Solina
- Sydani
- Others

## NSIPSS 1.0 (v2018)



## NSIPSS 2.0 (v2021)

<b>Vision</b>	Achieve greater than 80% immunization coverage for ALL antigens in Nigeria by 2028	<b>To have ALL infants in NIGERIA fully protected against vaccine preventable diseases</b>
<b>Objectives</b>	<ol style="list-style-type: none"> <li>1. Strengthen leadership and accountability</li> <li>2. Strengthen coordination for RI programs</li> <li>3. Improve issue detection and responsiveness in RI</li> <li>4. Increase data visibility, quality and use for action at all levels</li> <li>5. Increase fixed and outreach services for immunization especially in the very low performing states</li> </ol>	<ol style="list-style-type: none"> <li><b>1. Reduce the number of under-immunized children with Penta3 by 20% by 2024.</b></li> <li><b>2. Reduce the number of zero doses for Penta1 by 35% by 2024.</b></li> <li><b>3. Increase national Penta3 coverage to 90% by 2028.</b></li> </ol>



# The Decision for vaccine Introduction in Nigeria Passes through Three (3) Main processes



## The Technical Team (NVSTT)

- ❑ New Vaccine Strategy Task Team (NVSTT)
- ❑ It is a vaccine introduction coordination team of NERICC and Made up of Govt and Partners
- ❑ Initiate and provide technical lead for the development of Application, training materials and Implementation
- ❑ Assessment and Evaluation of the vaccine uptake

## The Recommendation Team (NGI-TAG)

- ❑ Made up of expert from research, Academia, Regulatory body, CSOs, and other relevant stakeholders
- ❑ Provide recommendation on vaccine and delivery process

## Approval Team (CG, CG, ICC)

- ❑ Strategy Group most made of NPHCDA management and her technical partners.
- ❑ Core Group Manage up of Senior technical leads from all the Partners and Directors/ Head of WGs
- ❑ Inter-Agency Coordination Committee – Headed by HMH and Heads of Organizations and provide final Approval.



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## 03 Factors that influence decision for One Dose HPV vaccine introduction

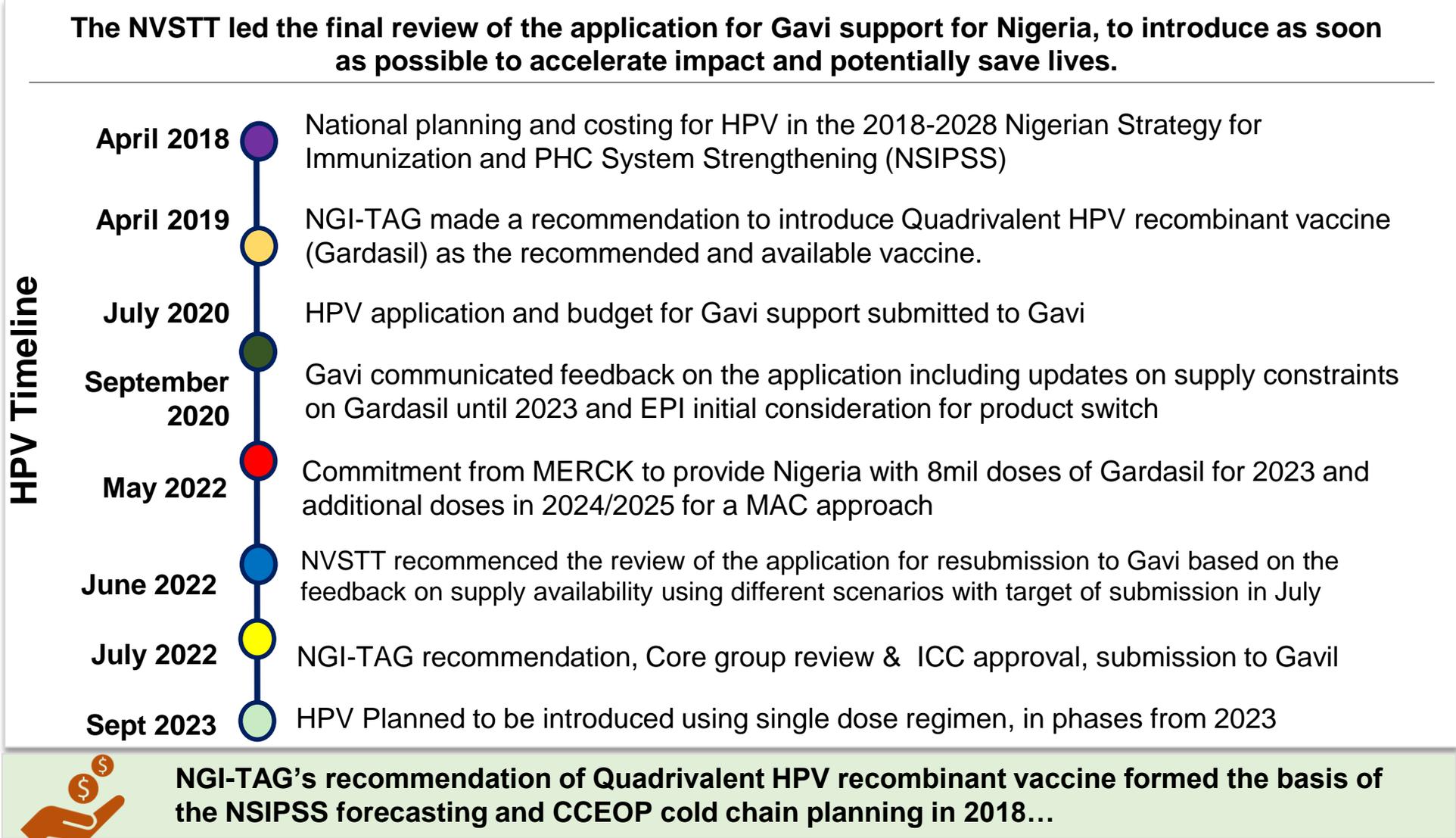
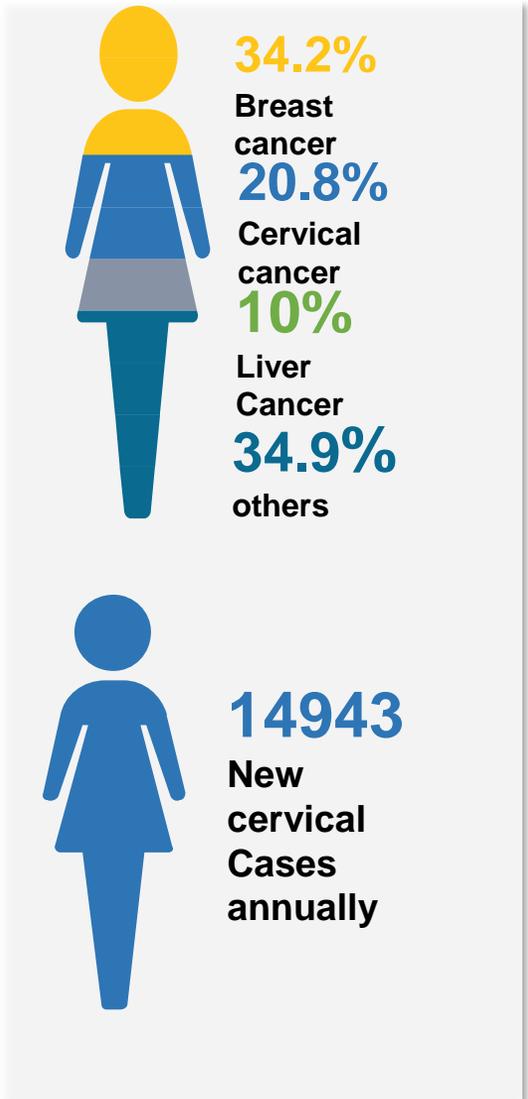
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...With the support of Gavi, Nigeria plans to introduce the HPV vaccine nationwide using a phased approach to sustain the country's focus on reducing morbidity and mortality from cervical cancer.



Source: <https://www.gavi.org/sites/default/files/document/guidelines/Detailed-product-profiles-072020.xlsx>



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# Factors that Influence the Country's Decision of Using Single Dose Regimen for HPV Vaccine Introduction



In Nigeria for factors play an important role in Decision making across all the major players of Decision for the NVI and during the One Dose Decision making

- 1 Vaccine Safety
- 2 Efficacy and Effectiveness
- 3 Vaccine availability
- 4 Economic and operational consideration



The Efforts from the New Vaccine Strategy Task Team (NVSTT)  
( Proposed scenarios for 2-dose HPV deployment)

...The NVSTT initially focus on the 2-Dose strategy, based on the available information that Gavi may not support 1-dose approach

2022, 97, 261–276

No 24



World Health Organization

Organisation mondiale de la Santé

Weekly epidemiological record  
Relevé épidémiologique hebdomadaire

17 JUNE 2022, 97th YEAR / 17 JUIN 2022, 97<sup>e</sup> ANNÉE  
No 24, 2022, 97, 261–276  
<http://www.who.int/wer>

Before revising the WHO Position Paper on HPV vaccination, WHO will conduct a stakeholder consultation on these important policy changes. **Expected in Dec, 2022**

**Gavi insight: IRC will not approve a single-dose introduction without the WHO position paper**

SAGE considered the evidence from a updated systematic review on the immunogenicity, efficacy, and duration of single-dose vaccination schedules compared with 2-dose schedules, and multidose schedules. The review included 55 studies, of which were new studies not included in a review conducted in 2014. The review showed **comparable efficacy and effectiveness of single- and multidose schedules in preventing persistent infection with HPV serotypes 16 and 18, lasting up to 10 years for both schedules**.

On the basis of recent data on efficacy and effectiveness, SAGE endorsed the optimal HPV vaccine schedules. **For 9–14-year-olds, national immunisation programmes can use either a single-dose or a 2-dose vaccination schedule with an interval between doses of at least 6 months.**

...based on the additional review of available information,

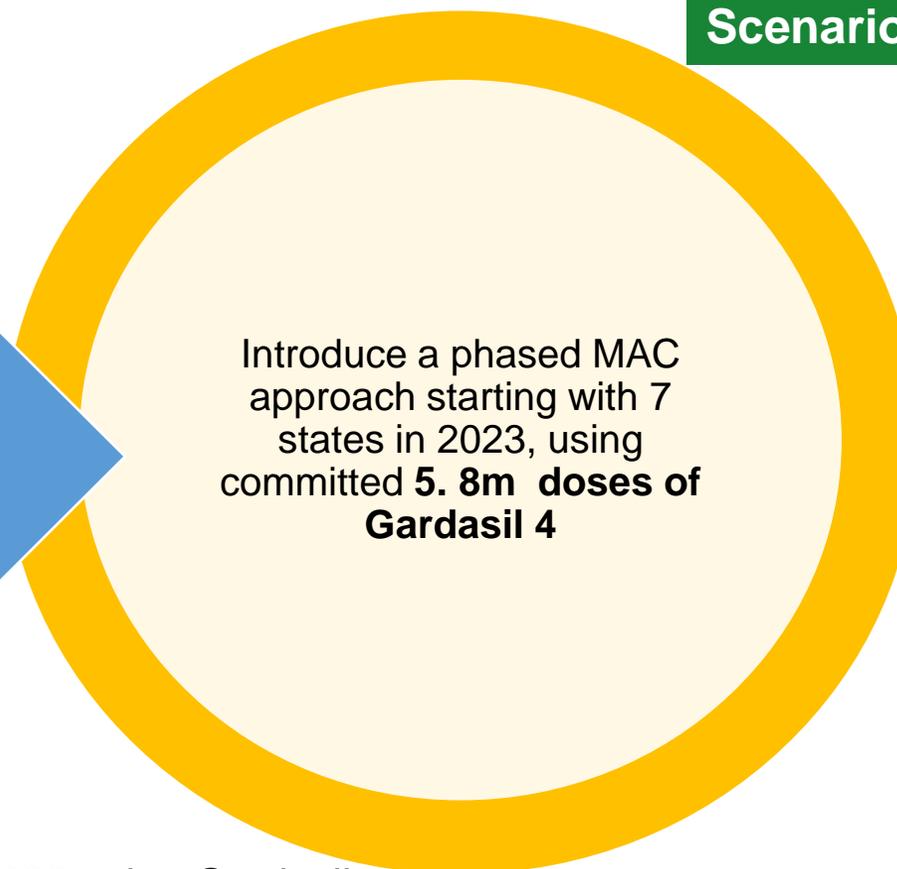
1. Vaccine availability is the main issue
2. Single dose option is not available for now, hence cannot be used to develop the application.

The NVSTT has developed and proposed the following scenarios for the rollout of HPV in Nigeria

### Scenario one



### Scenario Two



### Key comments:

- Vaccines will not be available for a MAC approach in 2023 using Gardasil
- Cecolin may be available for option one with possible product switch to Gardasil after the MAC.

...based on the additional review of vaccines availability, the NVSTT have developed the following scenarios for the rollout of HPV in Nigeria (1/2)

### Scenario 1: MAC approach for 2023 (Cecolin)

#### Year of introduction (2023)

- Introduction of HPV using a MAC approach ( 9-14yrs Females)
- School campaign and facility based & outreaches
- Target coverage of 80% for campaign
- Target coverage of 69% for routine (9 years)
- 2 dose
- Phased approach (12 state + FCT for phase 1 and 24 State phase 2)
- ❖ During and after the campaign, there will be HPV vaccines at the HFs
- ❖ **Total target population:**15,894,187
- ❖ **Total Vaccines required:** 32, 481,340

#### 2<sup>nd</sup> Year (2024)

- Routinize HPV vaccines to 9 years only
- 2 dose
- Facility based & school and community outreaches
- Target coverage 69%
- All 36+FCT to routinize the use of HPV
- ❖ **Total target population:**5,503,626
- ❖ **Total Vaccines required:**6,074,728

.....based on the additional review of vaccines availability, the NVSTT have developed the following scenarios for the rollout of HPV in Nigeria (2/2)

**Scenario 2:** Merck has committed to support the country with about 5.8m doses of HPV in 2023

### Year of introduction (2023)

- Introduction of HPV using a MAC approach ( 9-14yrs Females)
- Campaign and facility based & outreaches
- Target coverage of 80% for campaign
- Target coverage of 69% for routine (9 years)
- 2 dose
- ❖ **Total vaccines req: 5,974,007**
- ❖ **Target population: 3,485,533**
- Introduce in only 6 states + FCT

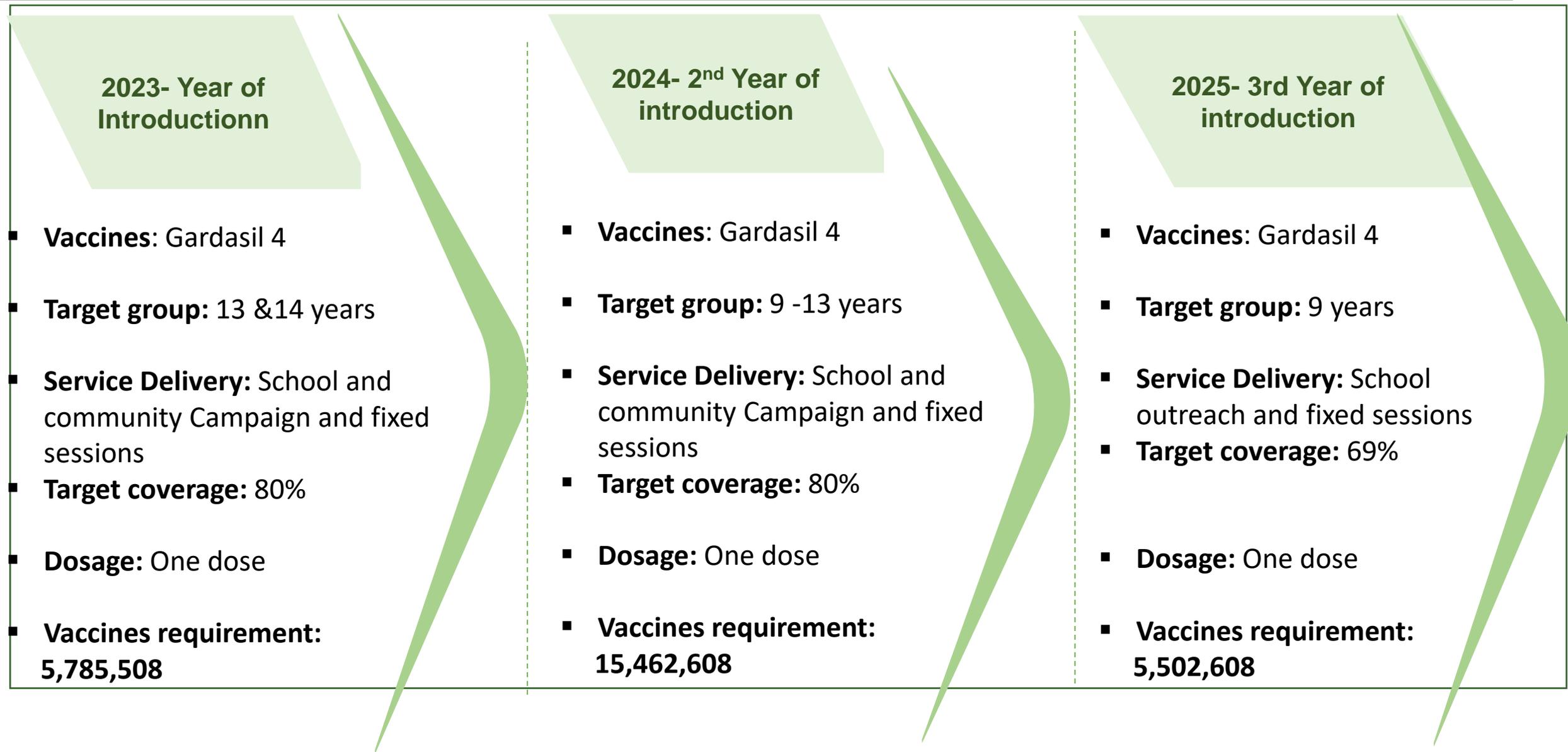
### 2<sup>nd</sup> Year (2024) – MAC

- Introduction of HPV using a MAC approach ( 9-14yrs Females)
- Campaign and facility based & outreaches
- Target coverage of 80% for campaign
- Target coverage of 69% for routine (9 years)
- 2 dose
- Phased approach (12 states phase 1 and 17 state phase 2)
- ❖ **Total vaccines req: 30,641,113**
- ❖ **Target population: 14,641,113**

### 3<sup>rd</sup> Year (2025)

- Routinized HPV vaccines to 9 years only
- 2 dose
- Facility based & outreaches
- Target coverage 69%
- All 36+FCT to routinize the use of HPV

...Outcome from the last meeting suggested the below rollout plan for HPV, Scenarios looking at tailored cohorts ....



The Efforts from the New Vaccine Strategy Task Team (NVSTT)  
( Proposed scenarios for 1-dose HPV deployment)

... The received an update that countries can consider one dose provided there is an alignment with the country's regulatory body ....

2022, 97, 261-276

No 24



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<http://www.who.int/wer>

Before revising the WHO Position Paper on HPV vaccination, WHO will conduct a stakeholder consultation on these important policy changes. **Expected in Dec, 2022**

**Revised insight: IRC may consider the application provided there is recommendation from NCI-TAG and alignment with Country's regulatory body**

SAGE considered the evidence from a systematic review on the immunogenicity, efficacy, and effectiveness of single-dose vaccination schedules compared with two-dose, and multidose schedules. The review included 55 studies, of which were new studies not included in a review conducted in 2014. The review showed **comparable efficacy and effectiveness for single- and multidose schedules in preventing persistent infection with HPV serotypes 16 and 18, lasting up to 10 years**.

On the basis of recent data on efficacy and effectiveness, SAGE endorsed the option of single-dose HPV vaccine schedules. **For 9-14-year-olds, national immunisation programmes can use either a single-dose or a 2-dose vaccination schedule with an interval between doses of at least 6 months.**

...based on the additional review of available information,

1. Updated commitment for vaccine availability in 2023, 2024 and 2025....
2. Single dose option was considered based on the available vaccine and SAGE's recommendation.

The NVSTT has developed phased modified MAC introduction in 2023 and 2024 and optimized modified approach from 2025 based on the vaccine availability.

## Phase 1 MAC in 2023

Introduce a MAC approach  
in 15 states and FCT in 2023  
Mix strategy- School  
campaign mode *and Routine*  
(*fixed and outreaches*)

## Phase 2 MAC in 2024

Introduce a MAC approach in  
21 states in 2024  
Mix strategy- School campaign  
mode *and Routine (fixed and*  
*outraches)*

### Key comments:

- Based on the MSD commitment of providing the required doses to the country through Gavi support
- From 2025, the country will routinize the HPV in the system and deploy a specialized optimize strategies with an extensive multi-sectoral collaboration to deploy the HPV to all the eligible girls.



# Outline



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## NGI-TAG Recommendation – The first recommendation by NGI-TAG in April 2019 – Gardasil 2-dose

In 2019, based on an appraisal of vaccine characteristics and Nigeria’s cold chain capacity the NGI-TAG recommended Quadrivalent HPV recombinant vaccine to be introduced into the EPI

Thematic Area	NGI-TAG Deliberation
<b>Rationale for Vaccine</b>	Evidence show that the prevalence of cervical cancer and other cancers in Nigeria remains high and pose greater socio-economic risk to the population, especially women. Review of available literature on profiles of HPV vaccine products demonstrates opportunity to reduce morbidity and mortality due to cervical cancers in the population. Therefore, the following draft recommendations are being tabled for consideration <sup>1</sup>
<b>Alignment with National Strategy</b>	Nigeria should introduce the HPV vaccine in its immunization programme in line with the proposed 2021 NVI timelines in the Nigeria Strategy for Immunization and PHC System Strengthening 2018 – 2028. The HPV introduction should target age group 9 – 14years.
<b>Product Recommendation</b>	Based on appraisal of the vaccine products on: efficacy and prevalence of serotypes (16 and 18) in Nigeria <sup>2</sup> , added protection against genital warts, and duration of protection; cost per fully immunized and cold chain capacity it is recommended that: ➤ <b><i>Quadrivalent HPV recombinant vaccine should be the vaccine of choice</i></b>
<b>Strategy Considerations</b>	The country should consider introduction of the HPV vaccine in both sexes (boys and girls) with a phased approach initially targeting girls, due to the burden of Cancer of cervix. In the medium to long term the country should improve on its immunization financing status and consider inclusion of HPV schedules for boys. The Nigeria Immunization Programme should use facility based & outreaches (in schools and out of schools) strategies for HPV introduction

Source: 1) NGI-TAG HPV Recommendation April 11, 2019; 2) 3.5% of women in Nigeria HPV 16/18 infection at a given time, 66.9% of invasive cervical cancers are attributed to HPVs 16 or 18: HPV 35 also seen associated with cervical cancers in Nigeria; WHO International Agency for Research on Cancer, 2018

## Request to NGI-TAG from the Country programme after Cecolin prequalification

Request for the review of the NGI-TAG recommendation in the mix of Gardasil vaccine shortage and the expected Cecolin prequalification in 2021.

- The request letter on the subject above dated **19<sup>th</sup> December 2020**, with reference **NPHCDA/ hereby refers**. The letter indicated among others the emergence of new evidence on vaccine availability and product preference for Human Papillomavirus vaccines:
  - **Gardasil HPV vaccine — improvement is expected in 2023**
  - **Cervarix HPV vaccine – To be available in 2023**
  - **Innovax HPV vaccine – To be available in 2022 and yet to be WHO prequalified.**

Following the deliberation by the NGI-TAG, the following decisions were made:

- Given the Gavi application guidelines on the introduction of the vaccine that the lead time of application to delivery of vaccines would take 24 months and following previous review on the available evidence on the various HPV vaccines, **the NGI-TAG maintains its initial recommendation of Gardasil as the product of choice**. While the country awaits the introduction of HPV vaccine, other public health measures such as cervical cancer screening should be strengthened.
- Guided by the NGI-TAG's recommendations in 2019 and 2021, Nigeria's previously planned for HPV introduction in 2021 with the 2- doses of quadrivalent HPV recombinant vaccine (Gardasil-4) as the preferred vaccine candidate.

# Request Letter from NPHCDA to NITAG for the Consideration of the Single Dose Introduction



National Primary Health Care Development Agency



Office of the Executive Director

NPHCDA/700/S.XVII/III  
06<sup>th</sup> July 2022

Professor Abdu-Aguye  
The Chairman  
Nigeria Immunization Technical Advisory Group

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E-mail: info@nphcda.gov.ng  
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## Request for Consideration of One-Dose Gardasil Vaccine Introduction into the National Immunization Programme

The National Primary Health Care Development Agency (NPHCDA) appreciates the support of the National Immunization Technical Advisory Group (NITAG) in improving access to vaccination through provision of experts' recommendation that result in refining the immunization landscape and smooth introduction of new vaccines into the programme.

The NITAG may recall in April 2019, the recommendation around HPV was Quadrivalent (GARDASIL4). The country has now received commitment of this vaccine from MERCK, 8million doses in 2023 and another 11million in 2024 for MAC and routinize fully from 2025.

In addition to the availability of GARDASIL4 vaccine, SAGE has recently provided additional evidence that one dose regimen of the vaccine is as good as two doses regimen.

The Federal Government of Nigeria through NPHCDA requests for your expert review and consideration for HPV introduction in the country using the single dose.

1. The NITAG earlier recommended introduction of two-Dose (2) schedule of Gardasil, into the routine immunization in Nigeria. However, recent updates revealed that one (1) dose Gardasil can equally provide required protection over the same period like two-dose schedule. *In view of this update can Nigeria introduce a one dose schedule for routine immunization in 2023?*

The timeline for the submission of the HPV application to Gavi is 18<sup>th</sup> July 2022, and the recommendation of NITAG is one of the mandatory requirements for the Gavi IRC for the submission of the application.

Therefore, the programme appreciates if NITAG will convene an emergency meeting to fast track the review of the recommendation of the HPV one-dose schedule, so that the country will meet up with the deadline of the submission.

Please, accept the assurances of my highest esteemed regards.

  
Dr. Faisal Shuaib MBBS, MPH, DrPH  
Executive Director/ CEO

**In line with NSIPSS(2018-2028), Nigeria planned to introduce HPV vaccine in 2021, however update from Gavi and the vaccine suppliers indicate that the vaccine of choice Gardasil-4 will be available earliest in 2023**



**FMoH through NPHCDA made a request to the NGI-TAG** to consider the introduction One-dose Quadrivalent HPV vaccine(GARDASIL-4) into the routine Immunization schedule.



**Research Question:**

1. Should Gardasil-4valent HPV single dose be introduced into Nigeria's Routine Immunization (RI) schedule for children aged 9-14years as against the previous 2 dose recommendation?

**...The evidence below shows that the one-dose protocol may be as effective as the multidose regimen in preventing HPV infection and precancerous lesions in healthy young women.**

	Kenya	Tanzania	India
<b>Title</b>	<b>KEN-SHE, (Efficacy)</b>	<b>DoRIS, (Immunogenicity)</b>	<b>IARC (Efficacy)</b>
Study design	Prospective, blinded, randomized study of single-dose	Randomised open-label trial in females	Randomized clinical trial comparing 2 versus 3 dose-regimens of Gardasil, with (~5000 subjects) having received only a single dose of vaccine
Study Target age	Females 15-20 years of age	9-14 years of age	females 10-18 years of age
Study objective	Vaccine efficacy of single dose HPV vaccination in preventing persistent HPV infections with Cervarix or Gardasil 9 compared to delayed vaccination	-Immunological Non-Inferiority 1 Dose vs 2-3 doses (seropositivity) at Month 24 -Immunological Non-Inferiority 1 Dose vs historical controls 10-25yrs	Efficacy of four-valent HPV vaccination in preventing persistent HPV-16/18 infections
Duration of the study	18 months analysis is available; follow-up ongoing till Month 36	Result at Month 24 (Update to 30 months)	Results at Year 10
Result	Single-dose Cervarix and Gardasil 9 vaccines were highly effective in preventing incident persistent oncogenic HPV infection <ul style="list-style-type: none"> <li>▪ 97.5% vaccine efficacy for HPV-16/18 persistent infections at Month 18 for both vaccines.</li> <li>▪ Efficacy estimates were similar to those reported for multidose regimens</li> </ul>	<ul style="list-style-type: none"> <li>▪ Single-dose of Cervarix is non-inferior to 1-dose in historical cohort (CVT)</li> <li>▪ Single-dose Gardasil 9 is non-inferior to 1-dose in historical cohort (India-IARC)</li> </ul>	Across the different schedules (single dose, 2-doses on 0,6 months and 3-dose on 0,1,6 months schedule) Gardasil VE against HPV-16/18 infections remains similarly high(>90%) up to at least 10 years post vaccination.

<sup>[1]</sup> Ruanne V. Barnabas et al., "Efficacy of Single-Dose HPV Vaccination among Young African Women," preprint (In Review, November 19, 2021), <https://doi.org/10.21203/rs.3.rs-1090565/v1>.

<sup>[2]</sup> Deborah Watson Jones et al., "Immunogenicity and Safety Results Comparing Single Dose Human Papillomavirus Vaccine with Two or Three Doses in Tanzanian Girls - the DoRIS Randomised Trial," *SSRN Electronic Journal*, 2022, <https://doi.org/10.2139/ssrn.4055429>.

<sup>[3]</sup> Partha Basu et al., "Vaccine Efficacy against Persistent Human Papillomavirus (HPV) 16/18 Infection at 10 Years after One, Two, and Three Doses of Quadrivalent HPV Vaccine in Girls in India: A Multicentre, Prospective, Cohort Study," *The Lancet Oncology* 22, no. 11 (November 1, 2021): 1518–29, [https://doi.org/10.1016/S1470-2045\(21\)00453-8](https://doi.org/10.1016/S1470-2045(21)00453-8).

# Single Dose Recommendations

Should Gardasil-4 valent HPV single dose be introduced into Nigeria's Routine Immunization (RI) schedule for children aged 9-14 years as against the previous 2 dose recommended?

## Summary of the available evidence for Gardasil Quadrivalent HPV vaccine:

- 95%-98% efficacy of the single dose schedule which is quite comparable to a two or three dose schedule
- For effectiveness, there is 88.9% after the vaccination of a single dose for serotype 6, 11, 16 & 18
- Increased availability of the vaccine for persons especially in low and medium -income countries with high population numbers. Specifically, Nigeria has secured a supply commitment of 8 million in 2023, 11.8million in 2024 and 3.2 million in 2025
- Introducing the single dose will alleviate current vaccine supply constraints, address challenges of dropout, ease logistics and delivery processes for the vaccines
- Single-dose regimen may reduce economic costs for introducing HPV vaccine by ~30 to 40+%.

Following current evidences that a single dose of the HPV vaccine provides as much protection as the initially recommended two or three dose schedules, the NGI-TAG recommends;

- ❖ Gardasil quadrivalent HPV 1-dose schedule to be included in the Routine Immunization program in Nigeria as a viable strategy to address her high burden of cervical cancer
- ❖ For programmatic preparedness, the HPV vaccination should commence by the third quarter of 2023.



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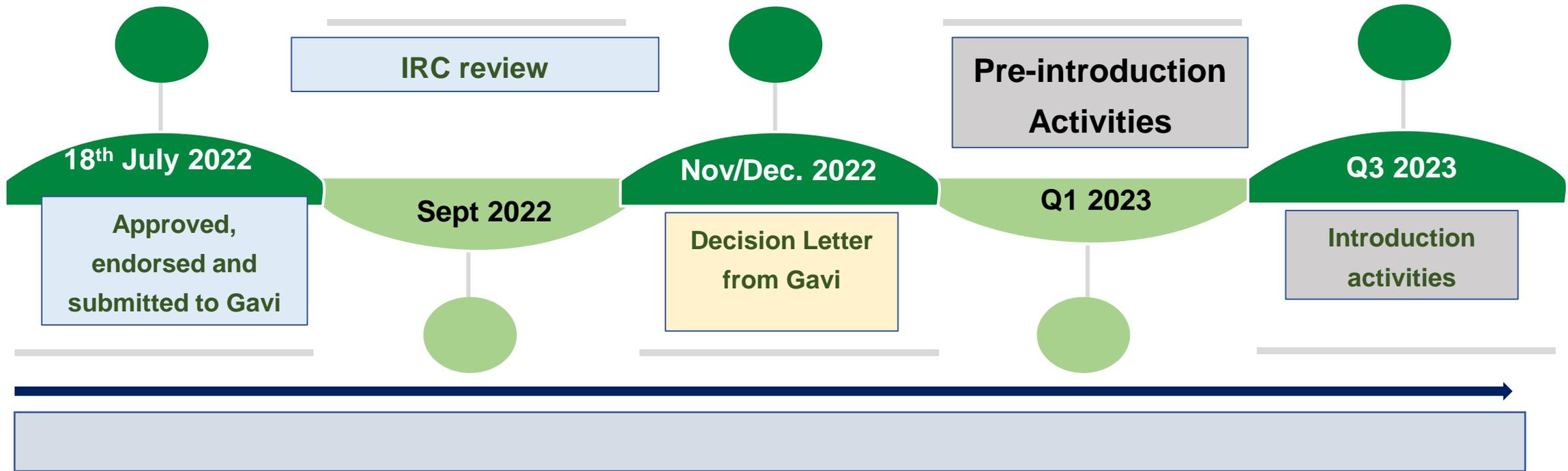


# The Position of the Country's Application

- The application was developed and submitted by the NVSTT (membership from both government and partners) and submitted to Gavi in July 2022.
- All the relevant endorsements and required documents submitted.
- The Country received pre-screening feedback from Gavi secretariat and areas of concerns were addressed.
- The country awaits the IRC review in 4<sup>th</sup> Quarter of 2022.

# The Projected timelines for the HPV introduction

HPV





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Challenges and Immediate Next Steps





# Challenges during the Decision Making and the Application Development



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- 1 The challenges on arrival at a programmatic consensus and alignment with management and strategy group based on the country's priority and the strategic goals.
- 2 Bringing together the stakeholders for the development of the application, engagements of both in-country and global team.
- 3 Delays in endorsements because of the impact this will have to the fiscal space (Finance), need for additional clarification by the MoF etc.
- 4 Meeting the requirements of Gavi, Cold Chain, and other updates, and also pre-screening feedback and updates.



## Immediate Next Steps



....

- 1 To commence early stakeholders' engagement to identify the extended stakeholders (Stakeholders from Educational sector, Research institutions and affiliates, stakeholders from Adolescent health, HIV/STI's programmes, Humanitarian interventions etc) to commence review of the existing advocacy, Risk Communication and the Community Engagement (RCCE).
- 2 Commence early development of the relevant training material for the HPV introduction training especially the RCCE.
- 3 Commence early ACSM activities at least six (6) months before the introduction.



*Thank you*