

# **Consideration for HPV vaccine** product choice

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**CHIC Southeast Asia and Western Pacific HPV Symposium** 



CHIC

# 144 Countries introduced HPV vaccination in national programme

**144 (74%)** countries introduced HPV vaccination

> **50 (26%)** countries did not introduce

> > 2030 Target: 194 countries

Date of slide: September 2024 Map production: Immunization Vaccines Biologicals (IVB), World Health Organization Data Source: WHO HPV vax Intro Dashboard



## Global HPV vaccine coverage among girls substantially increased

The positive trend observed since last year was confirmed and strong increases in first and final dose global HPV coverage among girls were registered in 2023.

Increase in HPV coverage is driven particularly by new introductions and programme expansion combined with encouraging signs of recovery of coverage in existing programmes.

All countries are included in global and regional calculations. Countries with HPV programmes but not reporting in 2023 are flatlined based on 2022 data.

Countries where HPV vaccine has not been introduced are included in the calculation of the estimate using a value of zero .

World Health Organization Unicef

### Global HPV Vaccine Coverage (%)



WUENIC 2023





# WHO recommendations\* on HPV vaccine schedule can optimize vaccine coverage

**Primary target**: Girls 9 to 14 years of age

**Schedule** \*: 2-dose schedule from 9 to 45 years old

Alternative: 1-dose schedule for 9 to 20-year-olds

<u>Prioritize</u>: - Immunocompromised/HIV+ - 2 doses, ideally 3 - Multi Age Catchup through 18 years at introduction

**Secondary Targets:** boys & older women/adults, if feasible and affordable

World Organ	ization Weekly epide Relevé épidém	emiological record niologique hebdomadaire			
Organisation mondiale	de la Santé No 50, 2022, 97th YEAR / 16 E No 50, 2022, 97, 645–672 http://www.who.int/wer	16 DICEMBER 2022, 97th YEAR / 16 DECEMBER 2022, 97-AINEE No 58, 2022, 97, 655-652 http://www.wbo.int/wer			
Contents 645 Human papillomavirus vaccines: WHO position paper (2022 update)	Human papillomavirus vaccines: WHO position paper (2022 update)	Vaccins contre les papillomavirus humains: note de synthèse de l'OMS (mise à jour de 2022)			
Sommaire 645 Vaccins contre les papillomavirus humairos: note de sputise de l'OMS (mise à jour de 2022)	Introduction In accordance with its mandate to provide normative gaidance to Member States on health policy matters, WHO issues a series of regularly updated position papers' on vaccines and combinations of vaccines against diseases that have an international public bealth impact. These gapers are concerned primarily with the use of vaccines in large-scale vaccination programmes.	Introduction Conformément à son mandat, qui prévoit qu'elle fournisse aux fatta Membres des orien- tations à caractere normatife mattiére de politique sanitaire, l'OMS publie une série de notes de synthèse régulièrement mises à jour sur les vaccins et les associations vacci- nales contre les maladies aynt une incidence sur la santé publique internationale. Ces notes portent principalement sur l'utilisation des vaccins dans le cadre de programmes de vacci- nation à grande chefle.			
	The vaccine position papers are drafted by the WHO SAGE Secretariat, they summarize estential background informa- tion on disease and vaccines and conclude with the current WHO position on the use- tion, the position papers are reviewed by a large group of external subject-matter experts and end-users. The Grading of Recommendations Assessment, Develop- ment and Evaluation (GRADE) and the poslikhed alongide the position papers are described on the WHO website. The position of vaccine posi- tion papers are described on the WHO website. The position of vaccine posi- tion papers are described on the KHO website. The position papers are intended for an or papers are intended for an or papers are intended for a paper subject of the state of the programmes. They may also be of interest to vaccine advisory groups, international funding agencies, health professionals,	Les notes de synthèse un les vaccins sont rédi- géres par les servicies auto ASGA de POMS, elles résument les informations essentielles sur les maladies et les vaccins associés et présentent en condusion la position actuelle de l'OMS ( PCM-DEI mondule. Avant leur mise en forme définitive, elles sont examinées par un large groupe d'expersite settemes et d'Utilisateurs finals. Les résultats de l'evaluation GRADE (Grading of Keommendations des Assessment, aux de données à l'appai des recommandations out publiés en même temps que la note de synthèse. Les méthodes employées par le notes de synthèse sur les vaccins sont décrites notes de synthèse sur les vaccins sont décrites la sante publique et aux administrateurs des programmes de vaccination, mais delles peuvent également présenter un intérêt pour les			
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### \* Contains off label recommendations

### ANY NEWS FOR NEXT SAGE?

Source: https://www.who.int/publications/i/item/who-wer9750-645-672

1-dose schedule➢ HICs as well as LMICs

WORLDWIDE

USE

/1-DOSE

**SCHDEULES** 

**PTIMIZED** 

- Many countries adopted 1-dose up to 20 years of age (some up to 25 yr)
- Several countries widened age ranges for catch-up

## 2-dose schedule

many HICs switched to 2-dose schedule in those 15 years and older



#### Disclaimer

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be



## Supply demand balance

Supply increases in recent years have led to a **significant reduction in the risk of <u>global</u> <b>shortages**. In the <u>short-term</u>, under the base supply scenario, access risks still exist if target populations significantly expand; in the low supply scenario this could result in shortages. In the <u>mid-long term</u>, excess supply will require appropriate management.

	Base Supply			Low Supply			
Demand Scenarios	Short-Term (1-3)	Mid-Term (4-6)	Long-Term (7-9)	Short-Term (1-3)	Mid-Term (4-6)	Long-Term (7-9)	
1. Base (w/MACs)							
2. Base (+ w/boys , MACs)							
3. Base (+w/boys, MACs, older age catch-up )							
4. 1-dose w/MACs							
5. 1-dose w/MACs (+boys)							
*Single dose schedule supporting data ass available since 2022 only for a limited num products	ber of Sup	ufficient supply ply <1.1X Demand	Some risk of sho Supply <1.3X Den	nand Supply	of shortages >1.3X Demand	Excess supply Supply > 2X Deman	

# Available HPV vaccines in the market



For complete information on HPV vaccine products see: https://www.who.int/publications/i/item/9789240089167

Trade Name	Cervarix™	Gardasil®	Gardasil-9®	Cecolin®	Walrinvax®	Cervavac®
Valency	Bivalent	Quadrivalent	Nonavalent	Bivalent	Bivalent	Quadrivalent
Manufacturer	GlaxoSmithKline Biologicals (GSK) Belgium	Merck/MSD USA	Merck/MSD USA	Xiamen Innovax Biotech Co. Limited China	Walvax Biotechnolog y Co. Limited China	Serum Institute of India (SII)
HPV types included	<mark>16/18</mark>	6/11/ <mark>16/18</mark>	<mark>6/11/<mark>16/18</mark>/31/33 /45/52/58</mark>	<mark>16/18</mark>	<mark>16/18</mark>	6/11/ <mark>16/18</mark>
Presentation	Single dose vial (0.5ml) Two Dose vial (1.0ml)	Single dose vial (0.5ml)	Single dose vial (0.5ml)	Single dose vial (0.5ml)	Single dose vial (0.5ml)	
WHO PQ decision	2009	2009	2018	2021	2024	To be submitted
Price HIC/UMIC <sup>1</sup>	\$27 (Median)	\$39 (Median)	\$101 (Median)			
Price PAHO RF <sup>2</sup>	-	\$ 10.48	-	\$2.9		
Price Gavi/UNICEF <sup>3</sup>	\$5.18	\$4.50		\$2.90	ТВС	
Data on 1-dose efficacy or immunobridging <sup>4</sup>	Yes	Yes	Yes	Yes	Immunobridging study planned	Immunobridging study ongoing since 2024

<sup>1</sup> WHO MI4A Global HPV market study 2022 <sup>2</sup> UNICEF https://www.unicef.org/supply/documents/human-papilloma-virus-hpv-vaccine-price-data
 3 PAHO Revolving fund <u>https://www.paho.org/en/documents/paho-revolving-fund-vaccine-prices-2022</u>
 4 WHO HPV Position Paper 2022 https://www.who.int/publications/i/item/who-wer9750

# Not all Products have efficacy data for 1-dose ... ... immunobridging pathway and status for new products

 "A single-dose schedule should be considered for those HPV vaccine products\* for which data on efficacy or <u>immunobridging to vaccines with proven single-</u> <u>dose efficacy are available</u>." (WHO HPV Position, 2022)

\*As per Dec 2022, products for which efficacy and immunogenicity data support use in a single-dose schedule include <u>Cervarix</u>, Gardasil and Gardasil9.

"Immunobridging refers to evidence that 6-month (peak) and 24month (plateau) antibody levels for a vaccine are comparable to those of vaccines with proven single-dose efficacy."

## Interim 6-month data Cecolin vs Gardasil immune response indicate non-inferiority at 6 months



**Fig. 3 Geometric mean concentration ratios at 6 months after Dose 1** HPV-16 and HPV-18 geometric mean concentration (GMC) ratios 6 months after Dose 1 between Cecolin 0, 6-month schedule and Gardasil 0, 6-month schedule with 95 % confidence intervals.

**Source**: Vaccine 2024 Apr 2;42(9):2290-2298. doi: 10.1016/j.vaccine.2024.02.077. Epub 2024 Mar 1.

## WHO reviewed 6 & 24-month data and concluded:

GMT levels (6 & 24m) following 1 dose of Cecolin are non-inferior to immune response following 1 dose of Gardasil, a product with 1-dose efficacy data.

As a result, <u>Cecolin\* has been added to list of vaccines</u> that can be used in 1-dose schedules (*off-label*)

Public data release of 24-month final trial data:

- IPV Conference 12-15 Nov 2024
- Article will be submitted ASAP

NITAGs in need of urgent decision making in relation to Cecolin can request PATH to present (confidential) data priori to publication of the data

\* Cecolin is WHO PQ-ed and is licensed for use in females

# UPDATE!!!

- New update has been reflected in the <u>2<sup>nd</sup> edition</u> of WHO guidance "Considerations for HPV Vaccine Product Choice"
  - **1. Cecolin** one-dose evidence is available
  - 2. Prequalification of Walrinvax

**Considerations for** 0 Human **Papillomavirus (HPV)** Vaccine Product **Choice**, second edition



### WHO HPV Vaccine Introduction & Country Coverage Dashboard

This dashboard provides information about the status of HPV vaccine introduction in WHO Member States. As per the Global Strategy for Cervical Cancer Elimination, each country should introduce HPV in the national immunization stedule by 2030 and meet the target of 90% of girls fully vaccinated with HPV vaccine by age 15. Detailed information on the definition and data source of each indicator can be found in the Netadata page.

				-	
National schedule	Year of introduction	Delivery strategy	Targeted Age	Targeted Sex	Schedule (interval between doses
Yes	2010	School-based	13	Female	1 dose
					<u>.</u>

Malaysia

#### HPV vaccine, programme coverage in female



# **HPV** resources

## **HPV Vaccine Introduction Clearing House**

### Visit each area for related resources:



POLICY & DECISION-MAKING

Informing national decision-making for HPV vaccine introduction



### PLANNING

Planning for HPV vaccine introduction



### FINANCING

Budgeting and financing for HPV vaccine introduction



### VACCINES & SAFETY

Characteristics, presentations and safety profiles of HPV vaccines



### COMMUNICATION

Communicating effectively using research-based approaches



### IMPLEMENTATION

Delivering HPV vaccination programmes



### MONITORING & SURVEILLANCE

Monitoring the coverage and impact of HPV vaccine programmes



### HPV PARTNERS

Links to HPV partners and resources



