APRIL 2020

GARDASIL - Gavi

Merck & Co.

Submitted as part of Access Accelerated



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The information in this report has been submitted by the company concerned to the Access Observatory as part of its commitment to Access Accelerated. The information will be updated regularly. For more information about the Access Observatory go to www.accessobservatory.org

The information contained in this report is in the public domain and should be cited as: Merck & Co., GARDASIL - Gavi (2020), Access Accelerated Boston, US 2020 (online) available from www.accessobservatory.org

Program Description

Program Overview

Program Name

GARDASIL - Gavi

2 Diseases program aims to address

Cancer (cervical)

- 3 Beneficiary population
- Women

4 Countries

- Armenia
- Bangladesh
- Benin
- Bolivia
- Burkina Faso
- Burundi
- Cambodia
- Cte d'Ivoire
- Ethiopia
- Ghana
- Guyana
- Honduras
- Indonesia
- Kenya
- Lao PDR
- Liberia
- Madagascar
- Malawi
- Mali
- Niger
- Rwanda
- Sao Tome and Principe
- Senegal
- Sierra Leone
- Solomon Islands
- Sri Lanka
- Tanzania
- The Gambia
- Togo
- Uganda
- Uzbekistan
- Zimbabwe
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5 Program start date

January 1, 2013

6 Anticipated program completion date Completion date not specified.

Contact person

Brendan Cooley (brendan_cooley@merck.com)

8 Program summary

Merck has offered an access price for GARDASIL to all Gavi-supported countries. Merck's commitment to helping protect global health by improving the affordability, availability, accessibility, and use of our vaccines around the world is fundamental to our business and overall mission. We offer GARDASIL at an access price that is significantly less than the price of these vaccines in developed markets. This price is exclusive to the public sectors of the countries eligible for support from Gavi.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	Merck supports countries in awareness and community mobilization on cervical cancer

Strategy 2: Health Service Strengthening

ACTIVITY	DESCRIPTION
Planning	Merck supports countries in the planning and implementation of vaccination programs.
Management	Support for safety surveillance is provided if desired by the Ministry of Health.

Strategy 3: Price Scheme

ΑCTIVITY	DESCRIPTION
Price Scheme	Merck's access price is exclusive to the public sectors of the countries eligible for support from Gavi. More information can be found at: https://www.msdresponsibility.com/access-to-health/vaccines/

10 Strategy by country

STRATEGY	COUNTRY
Community Awareness and Linkage to Care	All countries
Health Service Strengthening	All countries
Price Scheme	All countries

Companies, Partners & Stakeholders

Company roles

COMPANY	ROLE
Merck & Co., Inc.	Merck has offered an access price for GARDASIL to all Gavi-supported countries.

¹² Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
GAVI Alliance	Gavi is responsible for co-funding the initiative through donor funding, along with the indi- vidual country co-financing.	Voluntary
	www.gavi.org	
UNICEF	UNICEF is responsible for tendering and procurement for Gavi-supported vaccine supply.	Voluntary

¹³ Funding and implementing partners by country

PARTNER	COUNTRY
GAVI Alliance	All countries.
UNICEF	All countries.

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT
Government	Merck provides support, as needed, to Ministries of Health for vaccine implementation, including training on safety/reporting adverse events following immunization (AEFI), programmatic planning and monitoring.

Local Context, Equity & Sustainability

15	Local health needs addressed by program
[No	response provided]
	a How needs were assessed
	[No response provided]
	Formal needs assessment conducted
	[No response provided]
16	Social inequity addressed
No.	
17	Local policies, practices, and laws considered during program design
	pient countries take responsibility and ownership to assess local priorities, regulations and requirements of their country prior to lying for access to GARDASIL through Gavi.
18	How diversion of resources from other public health priorities are avoided
[No	response provided]
19 Yes.	Program provides health technologies (medical devices, medicines, and vaccines)
20	Health technologies are part of local standard treatment guidelines
N/A	
21	Health technologies are covered by local health insurance schemes
N/A	
22	Program provides medicines listed on the National Essential Medicines List
N/A	
23	Sustainability plan
ln 2(015, Merck extended the current Gavi price GARDASIL through 2025 to Gavi-graduated countries. This action greatly assists in meet

ing the needs of low- and lower-middle-income countries by facilitating access to these vaccines in those countries while also making sure they remain affordable and sustainable in the long term.

Additional Program Information

Additional program information
[No response provided]

 Potential conflict of interest discussed with government entity
[No response provided]

 Access Accelerated Initiative participant
Yes.

 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership
Yes.

Program Indicators

Not yet available for this program

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Appendix

This program report is based on the information gathered from the Access Observatory questionnaire below.

Program Description

PROGRAM OVERVIEW

Program Name

2 Diseases program aims to address:

Please identify the disease(s) that your program aims to address (select all that apply).

Beneficiary population

Please identify the beneficiary population of this program (select all that apply).

4 Countries

Please select all countries that this program is being implemented in (select all that apply).

5 Program Start Date

- 6 Anticipated Program Completion Date
- Contact person

On the public profile for this program, if you would like to display a contact person for this program, please list the name and email address here (i.e. someone from the public could email with questions about this program profile and data).

Program summary

Please provide a brief summary of your program including program objectives (e.g., the intended purposes and expected results of the program; if a pilot program, please note this). Please provide a URL, if available. Please limit replies to 750 words.

PROGRAM STRATEGIES & ACTIVITIES

9 Strategies and activities

Based on the BUSPH Taxonomy of Strategies, which strategy or strategies apply to your program (please select all that apply)?

Strategy by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g. some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

Company roles

Please identify all pharmaceutical companies, including yours, who are collaborating on this program:

What role does each company play in the implementation of your program?

Funding and implementing partners

Please identify all funding and implementing partners who are supporting the implementation of this program (Implementing partners is defined as either an associate government or non-government entity or agency that supplements the works of a larger organization or agency by helping to carry out institutional arrangements in line with the larger organization's goals and objectives.)

- a. What role does each partner play in the implementation of your program? Please give background on the organization and describe the nature of the relationship between the organization and your company. Describe the local team's responsibilities for the program, with reference to the program strategies and activities. (response required for each partner selected).
- b. For each partner, please categorize them as either a Public Sector, Private Sector, or Voluntary Sector partner.
 (Public Sector is defined as government; Private Sector is defined

as A business unit established, owned, and operated by private individuals for profit, instead of by or for any government or its agencies. Generation and return of profit to its owners or shareholders is emphasized; Voluntary Sector is defined as Organizations whose purpose is to benefit and enrich society, often without profit as a motive and with little or no government intervention. Unlike the private sector where the generation and return of profit to its owners is emphasized, money raised or earned by an organization in the voluntary sector is usually invested back into the community or the organization itself (ex. Charities, foundations, advocacy groups etc.))

c. Please provide the URL to the partner organizations' webpages

13 Funding and implementing partners by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g., some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (funding and implementing partners), please identify which country/countries these apply.

14 Stakeholders

Please describe how you have engaged with any of these local stakeholders in the planning and/or implementation of this program. (Stakeholders defined as individuals or entities who are involved in or affected by the execution or outcome of a project and may have influence and authority to dictate whether a project is a success or not (ex. Ministry of Health, NGO, Faith-based organization, etc.). Select all that apply.

- Government, please explain
- Non-Government Organization (NGO), please explain
- Faith-based organization, please explain
- Commercial sector, please explain
- Local hospitals/health facilities, please explain
- Local universities, please explain
- Other, please explain

LOCAL CONTEXT, EQUITY & SUSTAINABILITY

15 Local health needs addressed by program

Please describe how your program is responsive to local health needs and challenges (e.g., how you decided and worked together with local partners to determine that this program was appropriate for this context)? How were needs assessed

Was a formal need assessment conducted

(Yes/No) If yes, please upload file or provide URL.

¹⁶ Social inequity addressed

Does your program aim to address social inequity in any way (if yes, please explain). (Inequity is defined as lack of fairness or justice. Sometime 'social disparities,''structural barriers' and 'oppression and discrimination' are used to describe the same phenomenon. In social sciences and public health social inequities refer to the systematic lack of fairness or justice related to gender, ethnicity, geographical location and religion. These unequal social relations and structures of power operate to produce experiences of inequitable health outcomes, treatment and access to care. Health and social programs are often designed with the aim to address the lack of fairness and adjust for these systematic failures of systems or policies.*)

*Reference: The definition was adapted from Ingram R et al. Social Inequities and Mental Health: A Scoping Review. Vancouver: Study for Gender Inequities and Mental Health, 2013.

Local policies, practices, and laws considered during program design

How have local policies, practices, and laws (e.g., infrastructure development regulations, education requirements, etc.) been taken into consideration when designing the program?

¹⁸ How diversion of resources from other public health priorities is avoided

Please explain how the program avoids diverting resources away from other public health priorities? (e.g. local human resources involved in program implementation diverted from other programs or activities).

Program provides health technologies

Does your program include health technologies (health technologies include medical devices, medicines, and vaccines developed to solve a health problem and improve quality of lives)? (Yes/No)

²⁰ Health technology(ies) are part of local standard treatment guidelines

Are the health technology(ies) which are part of your program part of local standard treatment guidelines? (Yes/No) If not, what was the local need for these technologies?

(1) Health technologies are covered by local health insurance schemes

Does your program include health technologies that are covered by local health insurance schemes? (Yes/No) If not, what are the local needs for these technologies?

⁽²⁾ Program provides medicines listed on the National Essential Medicines List

Does your program include medicines that are listed on the National Essential Medicines List? (Yes/No) If not, what was the local need for these technologies?

23 Sustainability plan

If applicable, please describe how you have planned for sustainability of the implementation of your program (ex. Creating a transition plan from your company to the local government during the development of the program).

ADDITIONAL PROGRAM INFORMATION

24 Additional program information

Is there any additional information that you would like to add about your program that has not been collected in other sections of the form?

Potential conflict of interest discussed with government entity

Have you discussed with governmental entity potential conflicts of interest between the social aims of your program and your business activities? (Yes/No) If yes, please provide more details and the name of the government entity.

25 Access Accelerated Initiative participant

Is this program part of the Access Accelerated Initiative? (Yes/No)

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Is your company a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)? (Yes/No)

Program Indicators

INDICATOR DESCRIPTION

27 List of indicator data to be reported into Access Observatory database

For this program, activities, please select all inputs and impacts for which you plan to collect and report data into this database.

28 Data source

For this indicator, please select the data source(s) you will rely on.

Prequency of reporting

Indicate the frequency with which data for this indicator can be submitted to the Observatory.

30 Data collection

- a. Responsible party: For this indicator, please indicate the party/parties responsible for data collection.
- b. Data collection Description: Please briefly describe the data source and collection procedure in detail.
- c. Data collection Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

- a. Responsible party: Please indicate all parties that conduct any processing of this data.
- b. Data processing— Description: Please briefly describe all processing procedures the data go through. Be explicit in describing the procedures, who enacts them, and the frequency of processing.
- c. Data processing Frequency: What is the frequency with which this data is processed?

32 Data validation

Description: Describe the process (if any) your company uses to validate the quality of the data sent from the local team.

³³ Challenges in data collection and steps to address challenges

Please indicate any challenges that you have in collecting data for this indicator and what you are doing to address those challenges.