

APRIL 2018

GARDASIL - Haiti, Zanmi Lasante

Merck & Co.

Submitted as part of Access Accelerated

Contents

Program Description	3
Program Overview	4
Program Strategies & Activities	5
Companies, Partners & Stakeholders	6
Local Context, Equity & Sustainability	7
Additional Program Information	8
Resources	9
Program Indicators	10
Appendix	11

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 - Haiti, Zanmi Lasante (2018), Access Observatory Boston, US 2018 (online) available from www.accessobservatory.org

Program Description

Program Overview

1 Program Name

GARDASIL - Haiti, Zanmi Lasante

2 Diseases program aims to address

- Cancer (cervical)

3 Beneficiary population

- Women
- People with low income

4 Countries

- Haiti

5 Program start date

January 1, 2016

6 Anticipated program completion date

December 31, 2018

7 Contact person

Brendan Cooley (brendan_cooley@merck.com)

8 Program summary

The purpose of this program is to prevent and reduce the high burden of cervical cancer in Haiti through increased access to human papillomavirus (HPV) vaccination. The specific objectives include:

1. Demonstrating feasibility and acceptance of HPV vaccination in select regions of Haiti.
2. Enabling local organizations and institutions in Haiti to gain operational experience in designing and implementing HPV vaccination projects.

To achieve this, Merck has joined with the local partner, Zanmi Lasante, a well-known and highly regarded entity by the Haitian Ministry of Health and the local population. Merck's main activity in supporting this program involves the donation of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]. The HPV Types 16 and 18 account for more than 60% of diagnosed cases in Haiti according to 2012 data.¹ Zanmi Lasante is responsible for planning and executing the program activities with Merck's support. Activities include education campaigns to raise awareness about cervical cancer, HPV and the HPV vaccine in rural and urban towns alike. These are conducted in partnership with local community leaders, schools, educators and local health teams.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	Merck is supporting Zanmi Lasante in awareness and community mobilization on cervical cancer.

Strategy 2: Medicine Donation

ACTIVITY	DESCRIPTION
Donation	Merck has donated enough GARDASIL to provide vaccination to approximately 30,000 individuals.
Delivery	An HPV vaccine delivery strategy is being developed based on past lessons learned that provides the greatest opportunity to reach the targeted population.

10 Strategy by country

STRATEGY	COUNTRY
Community Awareness and Linkage to Care	Haiti
Medicine Donation	Haiti

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Merck & Co., Inc.	Merck's main activity in supporting this program involves the donation of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Zanmi Lasante	Zanmi Lasante's role in the program is coordination, implementation and delivery of vaccination to targeted young girls in select regions of Haiti. These activities are in coordination with the Ministry of Health. http://zanmilasante.org/ ; https://www.pih.org/country/haiti	Voluntary

13 Funding and implementing partners by country

PARTNER	COUNTRY
Zanmi Lasante	Haiti

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.
NGO	Merck has partnered with Zanmi Lasante to guide planning for mobilization, implementation and safety monitoring for the vaccination program.

Local Context, Equity & Sustainability

15 Local health needs addressed by program

Cervical cancer carries a substantial burden in Haiti, and other low-resource settings. However, Haiti has yet to initiate an HPV vaccination program to address this burden. This program responds to the challenges of adoption of such a program in a low-resource setting.

16 Social inequity addressed

None.

17 Local policies, practices, and laws considered during program design

The Gardasil Haiti program was designed and implemented in close partnership with the Haitian Ministry of Health in order to ensure full compliance with local policies.

18 How program meets or exceeds local standards

[No response provided].

19 Program provides health technologies (medical devices, medicines, and vaccines)

Yes.

20 Health technologies are part of local standard treatment guidelines

Yes.

21 Health technologies are covered by local health insurance schemes

No. Though Gardasil is not covered by local health insurance in Haiti, it is very important in preventing cervical cancer caused by Human Papilloma Virus (HPV).

22 Program provides medicines listed on the National Essential Medicines List

No. Gardasil is very important in preventing cervical cancer caused by Human Papilloma Virus (HPV).

23 Sustainability plan

The results of the program are anticipated to be used by the Ministry of Health in prioritizing and applying for a Gavi-supported HPV vaccination program.

Additional Program Information

24 Additional program
information

[No response provided].

25 Access Accelerated Initiative
participant

Yes.

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

Yes.

Resources

1. WHO/ICO Information Center on HPV and Cervical Cancer. Summary Report on HPV and Cervical Cancer Statistics in Haiti. Barcelona, Spain: 2017: <http://www.hpvcentre.net/statistics/reports/HTI.pdf>

Program Indicators

Not yet available for this program

Appendix

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

Program Description

PROGRAM OVERVIEW

1 Program Name

2 Diseases program aims to address:

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

3 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

7 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).

8 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)?

10 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 selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

11 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?

12 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 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)?

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.

17 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 program meets or exceeds local standards

Is there anything else that you would like to report on how your program meets or exceeds local standards?

19 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?

21 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?

22 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?

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.

29 Frequency of reporting

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

30 Data collection

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

31 Data processing

- Responsible party: Please indicate all parties that conduct any processing of this data.
- 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.
- 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.

