

## Information to Applicants about the GARDASIL<sup>®</sup> Access Program

The GARDASIL Access Program enables organizations and institutions in eligible lowest income countries to gain operational experience in the design and implementation of human papillomavirus (HPV) vaccination projects, with the goal of supporting the development of successful child and adolescent immunization models.

The GARDASIL Access Program plans to make available at least three million doses of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant] to qualifying organizations and institutions in eligible developing countries where approximately 80% of the world's cervical cancer cases occur.. The program accommodates proposals from applicants to design and implement smaller scale HPV vaccination projects, rather than nationwide programs. Endorsement by the Ministry of Health is a critical application prerequisite.

The GARDASIL Access Program is made possible by a pledge from Merck & Co., Inc<sup>1,1</sup> and is managed by Axios Healthcare Development (AHD), a U.S. non-profit organization, with strategic guidance provided by the independent GARDASIL Access Program Advisory Board, comprised of international public health experts.

AHD administers the program, reviews and approves applications based on recommendations from the Advisory Board, and coordinates delivery of donated vaccines to recipients. AHD employs technical assistance from Axios International, a public health consultancy specializing in developing and emerging countries.

The GARDASIL Access Program encourages applicants to follow WHO recommendations and guidelines for HPV vaccination as outlined in its April 2009 position paper that specify that HPV immunization programs should initially prioritize high coverage in the primary target population of **girls aged 9-10 through 13 years** ([www.who.int/wer/2009/wer8415.pdf](http://www.who.int/wer/2009/wer8415.pdf)) The GARDASIL Access Program will provide information and guidelines for health care workers on how to handle and administer the vaccine.

---

<sup>1</sup>

Merck & Co., Inc. (Whitehouse Station, NJ, USA) operates as Merck Sharp & Dohme (MSD) in most countries outside the United States

***What is GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant]?***

GARDASIL is a non-infectious recombinant quadrivalent vaccine prepared from the highly purified virus-like particles (VLPs) of the major capsid L1 protein of HPV types 6, 11, 16 and 18. The quadrivalent HPV VLP vaccine is a sterile liquid suspension that is prepared by combining the adsorbed VLPs of each HPV type and additional amounts of the aluminum containing adjuvant and the final purification buffer. The VLPs contain no viral DNA, they cannot infect cells, reproduce or cause disease.

GARDASIL is licensed by FDA for use among females 9 to 26 years of age to prevent cervical cancer, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18.

GARDASIL is contraindicated in individuals who are hypersensitive to the active substances or to any of the excipients of the vaccine.

The health care provider should inform the patient, parent or guardian that vaccination does not substitute for routine cervical cancer screening. Women who receive GARDASIL should continue to undergo cervical cancer screening per standard of care.

GARDASIL is not recommended for use in pregnant women.

Vaccination with GARDASIL may not result in protection in all vaccine recipients. GARDASIL is not intended to be used for treatment of active genital warts; cervical cancer; CIN, vulvar interepithelial neoplasia (VIN), or vaginal interepithelial neoplasia (VaIN). GARDASIL has not been shown to protect against disease due to other HPV types.

In clinical studies for GARDASIL, vaccine-related adverse experiences that were observed at a frequency of at least 1.0 percent among recipients of GARDASIL and also greater than those observed among recipients of placebo, respectively, were pain, swelling, erythema, fever, nausea, pruritis and dizziness. In addition, common post-marketing reports include vomiting and syncope.

**Dosage and administration for GARDASIL**

GARDASIL is a ready-to-use, three-dose, intramuscular vaccine. GARDASIL should be administered in three separate intramuscular injections in the upper arm or upper anterior thigh over a six-month period. The following dosage schedule is recommended: first dose at elected date, second dose two months after the first dose and the third dose six months after the first dose.

Please refer to the Prescribing Information for more information on GARDASIL.

***How to Apply***

Axios International invites interested organizations or institutions to submit their proposals/applications **twice a year** (September/March). Applicants who miss the deadline for proposal submission may wait for the next

call. However, they may submit their proposals on the understanding that they will only be reviewed at the next board meeting. Proposals received after the deadline will be kept until the next submission date is due.

Applicants interested in applying for GARDASIL® must complete a simple application that clearly demonstrates their proposal on how the institution intends to implement the program, ensure safety injection procedures and conduct monitoring and evaluation process. The application/proposal will be reviewed by a team of competent and experienced independent reviewers and an AHD Advisory Board.

Applications can be accessed on any of the following websites:

- Request the application by email: [GARDASILaccess@axiosint.com](mailto:GARDASILaccess@axiosint.com)
- Request the application by fax or post to Axios International.

For more information about GARDASIL® Access Program and the eligible countries

[www.GARDASILaccessprogram.org](http://www.GARDASILaccessprogram.org)

You may also download and print out this form from this web site. If you do not have access to the Internet, or would like an electronic copy of this document, please contact Axios International.

#### **Email, fax or post**

GARDASIL Access Program

Axios International

7, Boulevard de la Madeleine

75001 Paris

France

Phone: +33 144 860 760

Fax: +33 144 860 122

Email: [GARDASILaccess@axiosint.com](mailto:GARDASILaccess@axiosint.com)

#### ***The review process***

As soon as the application is received by Axios International, a rapid screening will be performed to ensure that the information provided is complete. Applicants will be contacted within five (5) days of receipt of their application and will be informed about the progress of their file. Additional information may be requested at this stage. If the application is complete, independent experts, commissioned by AHD, will review the proposal and give their recommendations to the Advisory Board. The Advisory Board will make a final review of the application/proposal at their bi-annual board meeting and give a recommendation to AHD. Thereafter;

1. The proposal is satisfactory and the Institution is recommended for inclusion in the GARDASIL Access Program

OR

2. Additional information or clarifications are required before recommendation can be made

### ***When the application is approved***

The applicant will receive an official letter to confirm that AHD has approved the Institution for inclusion in the GARDASIL<sup>®</sup> Access Program. Details concerning the quantity of GARDASIL, timescale, shipping schedules and shipping procedures will be defined in the approval note. The applicant should provide the exact shipping address and any other relevant information necessary for sending the vaccine to the country when completing the application. The applicant will be notified of shipment schedule as soon as the information is received from the shipper.

### ***Logistics***

The administration and use of GARDASIL requires the donation product to be approved for use in the country. If the vaccine is not approved for use, the applying institution must have a special import license and/or a waiver letter from the government to import this donation.

AHD, supported by Merck & Co., is offering GARDASIL free-of-charge and will cover the shipping costs and insurance up to the indicated port of entry in the countries. The recipient is responsible for all other charges thereafter.

### ***Dialogue and Reporting***

There will be an ongoing dialogue with institutions participating in the program. In addition, a progress report should be sent to AHD about 6 months after receipt of the vaccines. A standard template will be provided to each institution to facilitate the reporting process. Main Indicators tracked will concern GARDASIL data consumption, number of people vaccinated (1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> injections), number of centres involved, etc. The information from the application and the date of the regular progress reports will be entered into a database maintained by AHD. This database will provide data on the number of institutions participating in the GARDASIL Access Program, the reported number of patients receiving GARDASIL in each country and other relevant pragmatic information.

### ***Re-Supply of GARDASIL***

Once an institution has received the first donation of GARDASIL, the request for the remaining quantity will be automatic based on numbers reached compared to those approved by the advisory board. The donor commits to provide the complete dose of GARDASIL (3 schedules) to all patients that have received the first dose through the application process. The institution will be asked to provide a progress report detailing the quantity of GARDASIL<sup>®</sup> requested, the quantity used and number of patients reached as justification. AHD reserves the right to amend requests based on information collected on the program and usage of product.

**Eligible Countries**

The following countries are eligible to participate in the program:

Afghanistan	Cuba	Lao PDR	São Tomé
Angola	Djibouti	Lesotho	Senegal
Armenia	Eritrea	Liberia	Sierra Leone
Azerbaijan	Ethiopia	Madagascar	Solomon Islands
Bangladesh	Gambia	Malawi	Somalia
Benin	Georgia	Mali	Sri Lanka
Bhutan	Ghana	Mauritania	Sudan
Bolivia	Guinea	Moldova	Tajikistan
Burkina Faso	Guinea-Bissau	Mongolia	Timor Leste
Burundi	Guyana	Mozambique	Togo
Cambodia	Haiti	Myanmar	Tanzania
Cameroon	Honduras	Nepal	Uganda
Central African Republic	India	Nicaragua	Ukraine
Chad	Indonesia	Niger	Uzbekistan
Comoros	Kenya	Nigeria	Viet Nam
Congo	Kiribati	Pakistan	Yemen
Congo, Democratic Republic of	Korea, DPR	Papua New Guinea	Zambia
Côte d'Ivoire	Kyrgyz Republic	Rwanda	Zimbabwe