



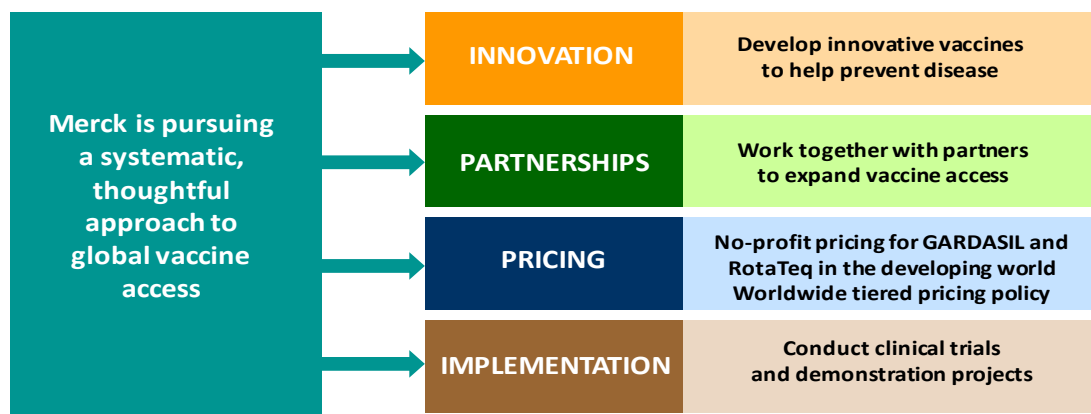
## Merck's Plan to Accelerate Access to Vaccines in the Developing World

We recognize that most people worldwide still lack adequate access to medicines, vaccines and healthcare. Because infectious diseases cause the greatest illness and death in the developing world, Merck believes we can have a significant impact on global health and can help to improve the lives of people around the world by expanding access to our innovative vaccines and infectious disease products. These access efforts support the Millennium Development Goals of the United Nations.



For more than 20 years, Merck has been at the forefront of the global response to the HIV/AIDS pandemic. Consistent with our HIV/AIDS access efforts, which began in 2001, Merck is taking steps to expand access to our vaccines including GARDASIL<sup>®</sup> [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] and RotaTeq<sup>®</sup> (Rotavirus Vaccine, Live, Oral, Pentavalent).

Merck's vaccine access strategy consists of the following four key pillars:



*"As the developer of some of the world's important vaccines, Merck has a responsibility to prevent disease and help save lives through vaccination. Merck is committed to reducing the gap between vaccine availability in developed countries and their introduction in the developing world. Our developing world strategy is a road map to making our vaccines accessible across the globe and supports Merck's mission of putting patients first."*

Margaret McGlynn  
President, Merck Vaccines and Infectious Diseases



<sup>1</sup> Developing world refers to the world's lowest-income countries as defined by the GAVI Alliance. These 72 countries are also referred to as GAVI-eligible countries, as they are eligible to apply for GAVI support.

**INNOVATION:** Vaccines have been hailed as one of the greatest public health success stories of the 20th century. Merck has a long-standing commitment to vaccine research and development and develops vaccines to help prevent diseases that cause suffering in both developing and developed countries.

Merck developed GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] to help prevent cervical cancer and other diseases caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18 and RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent) to help prevent rotavirus gastroenteritis in infants and children.

GARDASIL is indicated for use in girls and young women 9 through 26 years of age for the prevention of cervical, vulvar, and vaginal cancers caused by HPV Types 16 and 18; genital warts caused by HPV Types 6 and 11; and precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, and 18.

GARDASIL was designed to target four HPV Types: 6, 11, 16, and 18.

- Types 16 and 18 cause an estimated 70 percent of cervical cancer. It is also estimated that HPV Types 16 and 18 cause 40 to 50 percent of vulvar cancers and 70 percent of vaginal cancers, though the exact number of cases caused by these HPV types is unknown.
- Types 6 and 11 cause about 90 percent of genital warts as well as low-grade cervical and genital lesions.

### Cervical cancer

Every minute a woman is diagnosed with cervical cancer. Globally, approximately 500,000 women are diagnosed with cervical cancer each year.\* In the developing world, where access to screening and treatment is often limited, the burden of cervical cancer is high. Cervical cancer takes a heavy toll on families and societies, striking women in their most productive years, when they are involved in family and community life and make important economic contributions.

*\*Number represents all cervical cancer cases and not just those caused by HPV Types 16 and 18.*

RotaTeq is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3 and G4 contained in the vaccine.

### Rotavirus gastroenteritis

Rotavirus is highly contagious and a leading cause of severe diarrhea worldwide, infecting nearly all children by the age of 5 in both developed countries and the developing world. Rotavirus causes about 111 million cases of disease and two million hospitalizations each year. Worldwide about 600,000 children under 5 die from rotavirus each year, more than 80 percent of them in the developing world. In the United States, about 20 to 60 children die from rotavirus each year.



Merck is taking important first steps to expand access to vaccines including GARDASIL and RotaTeq in the developing world. The faster we improve access to vaccines like these, the more lives we can impact.

**PARTNERSHIPS:** Merck believes that ensuring access to vaccines in the developing world is a shared responsibility - no one organization can do it alone. Merck also believes that collaboration among industry, international, national and local organizations, governments, and non-governmental development organizations around the world is the best way to reduce vaccine preventable diseases in the developing world.

Merck is dedicated to finding innovative ways to bring vaccines to the developing world through partnerships and programs including:

*“Starting over 20 years ago, working with dozens of agencies, Merck provided more than half a billion free treatments for river blindness. Through other public-private partnerships, they reduced the HIV-positive rate in newborns in Botswana from about 40 percent to 4 percent.\*\* Now, the company is bringing that same commitment to expanding access to vaccines in some of the neediest areas of the world. We can only be grateful for their leadership in getting the public, private, and philanthropic talents of the world to work in harmony to improve global health.”*

William Foege, MD, MPH  
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\*For more information, see [www.mectizan.org](http://www.mectizan.org)  
\*\*For more information, see [www.achap.org](http://www.achap.org)

**GAVI Alliance (GAVI):** Merck, as part of industry, was a partner in the GAVI Alliance from the start. GAVI is a public-private partnership committed to saving children's lives and protecting people's health by increasing access to immunization in poor countries.

**GARDASIL Access Program:** In 2007, Merck made a commitment to donate at least 3 million doses of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] over five years to help address the problem of HPV infection in under-resourced communities. The GARDASIL Access Program is managed by Axios Healthcare Development, a United States nonprofit organization. In 2008, the Advisory Board of the GARDASIL Access Program recommended, and Axios Healthcare Development later approved, eight organizations in GAVI-eligible countries as the first recipients of GARDASIL through this donation program. In February 2009,

the first doses of donated GARDASIL were shipped. The program will draw upon learnings and experiences from participating organizations thereby contributing to the public knowledge base on HPV vaccine access in developing countries.

**RotaTeq Nicaragua Partnership:** Through an innovative donation and partnership program launched in 2006, Merck introduced RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent) in Nicaragua. This marked the first time there was access to a vaccine in the public sector of a developing country in the same year it was licensed in a developed country. By 2008, the partnership with the Nicaraguan Ministry of Health had achieved one of the highest rotavirus vaccination rates in the world with about 80 percent of eligible children in Nicaragua vaccinated with RotaTeq. In addition, Merck and the Nicaraguan Ministry of Health are working to strengthen Nicaragua's national rotavirus disease surveillance network and assess the public health benefits from the early adoption and use of a rotavirus vaccine.

**Merck Vaccine Network - Africa (MVN-A):** With funding from The Merck Company Foundation, the Merck Vaccine Network Africa (MVN-A) was launched in 2003 to help increase the capacity of immunization programs in Africa by supporting academic partnerships in the development of sustainable immunization training centers. More than 350 health professionals in Kenya and Mali have completed MVN-A training and returned to their country medical facilities to share their expertise. In 2007, two new MVN-A training centers were established in Uganda and Zambia.



**PRICING:** Based on the developing world's unmet needs, we decided to prioritize access to our rotavirus and cervical cancer vaccines. Merck will provide GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] and RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent) at no-profit prices to the public sectors of GAVI-eligible countries.<sup>1</sup> We recognize that pricing can be a barrier to access and believe that these lower prices, at which Merck does not profit, will greatly expand access to these innovative vaccines.

**Our Developing World Focus**  
72 GAVI-eligible countries



For other countries, Merck will create access by following a worldwide tiered pricing policy for vaccines, which is largely based on a country's ability to pay. Merck has followed a similar pricing policy for antiretrovirals.

Merck is also exploring other opportunities to lower cost, including manufacturing efficiencies and royalty reduction. Merck believes that pricing is an important and necessary component of expanding access, but pricing alone is not sufficient to improve public health and drive adoption.

**IMPLEMENTATION:** Merck conducts clinical trials and demonstration projects<sup>2</sup> to show how vaccines can be introduced in diverse regions and populations to help prevent disease and suffering around the world. Merck is committed to reducing the gap between vaccine availability in developed countries and their introduction in the developing world.

- Merck is partnering with PATH to conduct clinical trials and demonstration projects of vaccines in the developing world by providing vaccine and technical support at no cost.
  - PATH demonstration projects with GARDASIL are designed to support the acceleration of the availability of cervical cancer vaccines in the world's least-developed countries, and are ongoing in Peru, Vietnam and India.
  - PATH trials with RotaTeq are in progress in Bangladesh, Vietnam, Ghana, Kenya and Mali to better understand the efficacy and safety profile of the vaccine in developing world environments.
- Merck seeks World Health Organization (WHO) prequalification to facilitate purchasing of our vaccines by UN agencies like UNICEF.
  - GARDASIL (May 2009), RotaTeq (October 2008), and M-M-R®II (Measles, Mumps and Rubella Virus Vaccine Live) have received WHO prequalification.
- Merck is committed to registering our vaccines broadly around the world.
  - GARDASIL is approved in 111 countries, 23 of which are GAVI-eligible countries (through May 2009).
  - RotaTeq is approved in 90 countries, 15 of which are GAVI-eligible countries (through May 2009).



<sup>2</sup> A demonstration project evaluates the feasibility and impact of introducing a vaccine into a national immunization program.

More than 300,000 infants and children around the world are infected with rotavirus, and nearly 1,500 women are diagnosed with cervical cancer, every day. Merck is implementing a 4-point plan, based on innovation, partnerships, pricing and implementation, to improve access to its vaccines in the developing world where they are needed most.

Merck has begun taking steps to expand access to GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] and RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent) and will provide these two innovative vaccines at no-profit prices to the public sectors of GAVI-eligible countries. By expanding access to vaccines, Merck has an opportunity to make a significant contribution to global public health, and build on the Company's deep commitment to patient access.

Merck was ranked among the top three industry leaders by the Access to Medicines Index in 2008.

For more information on our access initiatives, please visit [www.merck.com/cr](http://www.merck.com/cr).



## Important Information about GARDASIL

### Indication

GARDASIL is a vaccine indicated in girls and women 9 to 26 years of age for the prevention of cervical, vulvar, and vaginal cancers; precancerous or dysplastic lesions; and genital warts caused by HPV Types 6, 11, 16, and 18.

GARDASIL does not substitute for routine cervical cancer screening, and women who receive GARDASIL should continue to undergo screening.

GARDASIL has not been demonstrated to provide protection against diseases from vaccine and non-vaccine HPV types to which a woman has previously been exposed through sexual activity.

GARDASIL is not intended to be used for treatment of active genital warts; cervical, vulvar, and vaginal cancers; cervical intraepithelial neoplasia, vulvar intraepithelial neoplasia, or vaginal intraepithelial neoplasia.

GARDASIL has not been demonstrated to protect against diseases due to HPV types not contained in the vaccine.

Not all vulvar and vaginal cancers are caused by HPV, and GARDASIL protects only against those vulvar and vaginal cancers caused by HPV Types 16 and 18.

### Select Safety Information

GARDASIL is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL.

GARDASIL is not recommended for use in pregnant women.

Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

The most common adverse reaction was headache. Common adverse reactions that were observed among recipients of GARDASIL at a frequency of at least 1.0% and greater than placebo were fever, nausea, dizziness; and injection-site pain, swelling, erythema, pruritus, and bruising.

### **Dosage and Administration**

GARDASIL should be administered in 3 separate intramuscular injections in the deltoid region of the upper arm or in the higher anterolateral area of the thigh over a 6-month period with the first dose at an elected date, the second dose 2 months after the first dose, and the third dose 6 months after the first dose.

**Before administering GARDASIL, please read the Prescribing Information and Patient Product Information, which are attached, and are also available at [www.gardasil.com](http://www.gardasil.com).**



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GARDASIL.pdf

### **Important Information about RotaTeq**

RotaTeq<sup>®</sup> (Rotavirus Vaccine, Live, Oral, Pentavalent) is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3, and G4 when administered as a 3-dose series to infants between the ages of 6 to 32 weeks. The first dose of RotaTeq should be administered between 6 and 12 weeks of age.

### **Select Safety Information**

RotaTeq should not be administered to infants with a demonstrated history of hypersensitivity to the vaccine or any component of the vaccine.

No safety or efficacy data are available for the administration of RotaTeq to infants who are potentially immunocompromised or to infants with a history of gastrointestinal disorders.

Caution is advised when considering whether to administer RotaTeq to individuals with immunodeficient contacts.

In clinical trials, the most common adverse events included diarrhea, vomiting, irritability, otitis media, nasopharyngitis, and bronchospasm.

In post-marketing experience, intussusception (including death) and Kawasaki disease have been reported in infants who have received RotaTeq.

RotaTeq may not protect all vaccine recipients against rotavirus.

**Before administering RotaTeq, please read the Prescribing Information and Patient Product Information, which are attached, and are also available at [www.rotateq.com](http://www.rotateq.com).**



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## Important Information about M-M-R®II

M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live) is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older.

M-M-R II should be given 1 month before or after administration of other live viral vaccines.

### Select Safety Information

M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live) is contraindicated in certain individuals, including those with: a history of hypersensitivity to any component of the vaccine, including gelatin; a history of anaphylactic or anaphylactoid reaction to neomycin; blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems; an immunodeficient condition or receiving immunosuppressive therapy; an active febrile illness; or those who are pregnant.

Due caution should be employed in administration of M-M-R II to persons with a history of cerebral injury, individual or family histories of convulsions, or any other condition in which stress due to fever should be avoided.

The following adverse reactions have been reported with M-M-R II without regard to causality: fever, headache, dizziness, rash, injection-site reactions, febrile convulsions, anaphylaxis and anaphylactoid reactions, arthritis, and thrombocytopenia.

As for any vaccine, vaccination with M-M-R II may not result in protection in 100 percent of vaccinees.

**Before administering M-M-R II, please read the Prescribing Information, which is attached, and is also available at [www.merck.com](http://www.merck.com).**



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