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NACI STRENGTHENS RECOMMENDATIONS ON ROTAVIRUS VACCINATION
Grade A recommendations for healthy and preterm infants

MONTREAL, Quebec, July 21, 2010 - This week, the National Advisory Committee on Immunization (NACI) updated and strengthened its statement related to the use of rotavirus vaccines in Canada. Rotavirus infection is the most common cause of severe gastroenteritis in children under the age of three. The NACI statement now includes Grade A recommendations (good evidence to recommend immunization) for healthy and preterm infants.

The strength of the new NACI recommendations rests in large part on the significant impact of RotaTeq® (rotavirus vaccine, live, oral, pentavalent) on the reduction and transmission of rotavirus in the United States, where Merck's rotavirus vaccine has been part of the government funded routine immunization of infants since 2006. In Canada, Merck's pentavalent rotavirus vaccine to prevent rotavirus gastroenteritis in infants has been available since 2006. More than 30 million doses of RotaTeq® have been distributed worldwide.

“The strengthened NACI statement refers to several US studies that have demonstrated considerable reductions in the number of gastroenteritis cases, hospitalizations and rotavirus-positive test results since the initiation of routine immunization with the pentavalent rotavirus vaccine among US infants in 2006,” said Dr. John Yaremko, a practicing paediatrician and Assistant Professor of Paediatrics at McGill University. “With the new NACI statement, provincial governments—none of which have implemented a universal publically-funded vaccination program—have a compelling document on which to base future decisions about rotavirus immunization.”

The Grade A NACI Recommendations are:

- **Healthy infants:** Rotavirus vaccine is recommended for infants with the immunization series beginning between 6 to 14 weeks plus 6 days of age.
- **Preterm infants:** Infants who are between 6 weeks (6 weeks and 0 days) and 8 months (8 months plus 0 days) of chronological age who are healthy and not hospitalized, can receive RotaTeq® or Rotarix™. The first dose should be given between 6 weeks (6 weeks and 0 days) and up to 15 weeks (14 weeks plus 6 days). The vaccination series should be completed by 8 months (8 months plus 0 days).

US data on RotaTeq® published

In the retrospective study published in *Pediatrics* and integrated into the latest NACI statement on the use of rotavirus vaccines, the impact of routine immunization of US infants with RotaTeq® was evaluated by the U.S. Centers for Disease Control and Prevention. The analysis demonstrated that the implementation of a public immunization program using Merck's pentavalent rotavirus vaccine resulted in a 67% decline in the number of rotavirus-positive test results in 2007-2008. Also, that when compared to the six previous seasons (2000-2006) in the United States, rotavirus activity during the 2007-2008 season was delayed by 15 weeks.¹ The NACI statement notes, "This reduction in rotavirus activity coincides with increased use of RotaTeq® following the recommendation of the Advisory Committee on Immunization Practices for universal immunization of US infants in February 2006."²

"For over 100 years Merck has been dedicated to discovering and developing new medicines and vaccines that contribute to the well-being of the population. We are proud of the real life dramatic reduction in rotavirus infection that RotaTeq® demonstrated in the United States and pleased that NACI incorporated these data in their new recommendations for the use of rotavirus vaccines in Canada," said Carlos Dourado, President of Merck in Canada.

Rotavirus is highly contagious and can lead to serious complications

Rotavirus is a highly contagious and unpredictable disease that infects almost all children (more than 95 per cent) at least once by the age of five.³ Symptoms can be mild to severe and generally last for three to nine days with up to 20 episodes of vomiting and/or diarrhea in a 24-hour period.^{4,5} Severe diarrhea and vomiting caused by rotavirus can lead to rapid and dangerous depletion of body fluids, which can be life-threatening.⁶

In Canada, up to 70 per cent of children hospitalized for gastroenteritis in the peak season are rotavirus positive.⁷ The strengthened NACI statement notes that approximately 15% of children with rotavirus visit an emergency department.

RotaTeq® prevented emergency department visits and hospitalizations

RotaTeq® is an oral vaccine that was approved for use in Canada in August 2006 for the prevention of rotavirus gastroenteritis caused by the serotypes G1, G2, G3, G4 and G-serotypes that contain P1A[8] when administered to infants.⁸ These rotavirus strains are responsible for approximately 90 per cent of rotavirus disease in North America, Europe and Australia.⁹ In clinical trials, the vaccine prevented 74 per cent of all rotavirus gastroenteritis cases and 98 per cent of the severe cases during the first full rotavirus season after completion of vaccination.¹⁰ The clinical trials program also showed that the vaccine prevented 94 per cent of rotavirus gastroenteritis-related emergency department visits and hospitalizations up to 3.1 years post-vaccination.

Today's NACI Statement also says, "In summary, postmarketing surveillance following distribution of more than 14 million doses of RotaTeq® in the US do not demonstrate or suggest an increased risk of intussusception or other serious adverse events among infants following RotaTeq® vaccine."¹¹

About NACI

The National Advisory Committee on Immunization (NACI) is a committee of recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health. The Committee reports to the Chief Public Health Officer of Canada, and works with departmental staff of the Centre for Infectious Disease Prevention and Control of the Public Health Agency of Canada to provide ongoing and timely medical, scientific and public health advice. NACI makes recommendations for the use of vaccines approved in Canada and also advises on the need for national vaccination strategies.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our medicines, vaccines, biologic therapies, and consumer and animal products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching programs that donate and deliver our products to the people who need them. Merck. Be Well. For more information, visit www.merck.com.

Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the proposed merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's and Schering-Plough's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period, due to, among other things, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2008 Annual Report on Form 10-K, Schering-Plough's Quarterly Report on Form 10-Q for the quarterly period ended Sept. 30, 2009, the proxy statement filed by Merck on June 25, 2009 and each company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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¹ Tate J E et al. Decline and Change in the Seasonal Patterns of Rotavirus Activity After the Introduction of Rotavirus Vaccine in the United States. *Pediatrics*. Volume 124, Number 2, August 2009.

² NACI Updated Statement on the use of Rotavirus Vaccines, *CCDR*, July 2010, Vol 36 pg 9

³ Parashar UD et al. *Emerg Infect Dis* 1998;4(4): 561-70

⁴ Musher D M, Musher B L. Contagious acute gastrointestinal infections. *N Engl J Med* 2004;351:2417-27.

⁵ Matson D O, In *Principles and Practice of Pediatric Infectious Diseases*. 2nd ed. Philadelphia, Pa: Elsevier Saunders; 2003. Chapter 232: section 1107.

⁶ Centres for Disease Control and Prevention, accessed at <http://www.cdc.gov/nip/diseases/rota/rotavirus.htm>.

⁷ Ford-Jones EL, Wang E, Petric M, et al. Hospitalization for Community-Acquired, Rotavirus-Associated Diarrhea. *Arch Pediatr Adolesc Med* 2000;154:578-585

⁸ RotaTeq® Product Monograph approved on December 11, 2009.

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¹⁰ Vesikari T et al. Safety and Efficacy of a Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine. *N Engl J Med* 2006;354;1:23-33

¹¹ NACI Updated Statement on the use of Rotavirus Vaccines, *CCDR*, July 2010, Vol 36 pg 6