FOR IMMEDIATE RELEASE

NACI Releases New Statement on Canada’s first Measles-Mumps-Rubella-Varicella Vaccine and Simultaneously Recommends Canadian Children Receive a Second Dose of Varicella Vaccine:

GlaxoSmithKline’s PRIORIX-TETRA™ could save children 2 additional injections

MISSISSAUGA, ON (October 27, 2010) Last week, Canada’s National Advisory Committee on Immunization (NACI) issued several statements including its recommendations for the use of PRIORIX-TETRA™; the first, and at present, the only measles-mumps-rubella-varicella (MMRV) combivalent vaccine authorized for use in Canada.

In a simultaneously issued statement, NACI has now recommended that all children receive a second dose of varicella vaccine at either 18 months or 4-6 years of age, which can be given in combination with the scheduled second dose of the Measles-Mumps-Rubella vaccine.

Manufactured by GlaxoSmithKline Inc., and authorized for market by Health Canada in July 2007, PRIORIX-TETRA™ is a live, attenuated vaccine indicated for active immunization against measles, mumps, rubella and varicella (the virus that causes chicken pox and shingles) in individuals from 9 months to 6 years-of-age (efficacy has not been evaluated in subjects above 6 years of age). PRIORIX-TETRA™ may be used in individuals up to 12 years-of-age based upon previous experience with the separate component vaccines, PRIORIX® (combined measles, mumps and rubella vaccine, live attenuated) and VARILRIX® [varicella virus vaccine, live, attenuated (OKA-strain)].

The measles-mumps-rubella (MMR) vaccine has been available in Canada since the 1970s, and the univalent varicella (chicken pox) vaccine has been available since 1998. However, until now these two vaccines could not be administered in the same syringe and therefore required a physician to give two injections at separate sites for each of the two doses recommended. One of the benefits of a combined MMRV vaccine is that its use would reduce the number of injections an infant may need to receive according to the provincial immunization strategy.

Presently, a number of Canadian provinces have adopted the use of PRIORIX-TETRA™ as part of their routine immunization program for the 12 month visit.

“The introduction of a new combination MMRV vaccine will now allow health care professionals, such as a community pediatrician, to be able to give parents the choice to potentially spare their child the potential pain of at least one (and potentially two) additional injections while combining protection against four vaccine-preventable diseases in a single two-dose combivalent vaccine.”, says Dr. Hirotaka Yamashiro, Chair, Pediatrics Section, Ontario Medical Association, Staff Physician, Hospital for Sick Children, and President, Pediatricians Alliance of Ontario.
For primary immunization with MMRV vaccine, the Grade-A NACI Recommendations are:

The first dose of MMRV is to be administered at 12-15 months, and the second at 18 months, or at 4-6 years-of-age (preschool). As stipulated in the product monograph, the doses may be administered closer together, with a minimum interval of 6 weeks between doses.

Since the most effective age for administering the second dose is currently unknown, the permissible range for the timing of the second dose allows jurisdictions with existing two-dose MMR programs to provide the second MMRV dose at 18 months or 4-6 years-of-age. Vaccine providers also have the option of providing the second dose anytime in between these two ages, for those who do not wish to wait until preschool to complete the two-dose series.ii

For two-dose varicella immunization, the Grade-A NACI Recommendations are:

Healthy children 12 months – 12 years-of-age receive two doses of varicella-containing vaccine (univalent varicella or MMRV) for primary immunization. A two-dose vaccine schedule is anticipated to further reduce varicella (both wild-type and breakthrough) disease incidence, increase herd immunity, potentially decrease disease outbreaks, as well as minimize the number of cases occurring in adolescents and adults (even with the anticipated shift to a higher mean age for varicella disease in a highly vaccinated population). Options for the choice of vaccine for the second varicella-containing dose depend on the vaccines and number of doses previously administered for primary immunization (univalent vaccine, MMR or MMRV).

For catch up immunization, the Grade-B NACI Recommendations are:

Two doses of MMRV a minimum of 6 weeks apart may also be administered up to 12 years of age as catch up for those not previously immunized with MMR and varicella vaccines, who are therefore susceptible to these vaccine-preventable diseases.

Children under 12 years-of-age, who have had only one dose of a varicella-containing vaccine should generally be offered a second dose as a catch-up. If the child has already received two doses of MMR previously, then the second varicella dose should be provided as a univalent varicella preparation. If the child has received only one dose of MMR, and one dose of varicella, then the second dose can be provided as MMRV, or as MMR and varicella separately.iii

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.
NACI recommendation for immunization: grades

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<td>A</td>
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<td>NACI concludes that there is fair evidence to recommend against immunization.</td>
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<td>I</td>
<td>NACI concludes that there is insufficient evidence (in either quantity and/or quality) to make a recommendation; however, other factors may influence decision making.</td>
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About GlaxoSmithKline Inc.

GlaxoSmithKline (GSK) is a leading research-based pharmaceutical company with a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better, and live longer. This mission gives GSK the purpose to develop innovative medicines, vaccines and healthcare solutions that help millions of people. GSK is consistently recognized as one of the 50 best employers in Canada and is a top 15 investor in Canadian research and development, contributing more than $144 million in 2009 alone. With a proud tradition of charitable and community support, GSK is designated a Caring Company by Imagine Canada. Discover more at GSK.ca.

About Measles, Mumps, Rubella and Varicella:

Measles

Measles is a highly contagious and acutely infectious disease caused by a virus. Symptoms include fever, cough, coryza (runny nose), conjunctivitis, Koplik spots (white spots on the inner lining of the mouth) and rash. Complications can include diarrhea, otitis media, bronchopneumonia, encephalitis and in rare cases, subacute sclerosing panencephalitis (SSPE). Measles (rubeola) is a leading cause of vaccine-preventable deaths in children worldwide.

In 1995, Canada's Conference of Federal/Provincial/Territorial Deputy Ministers of Health endorsed a national goal of measles elimination. Nationally, sustained transmission has been eliminated by the current 2-dose measles immunization programs and high vaccine coverage in the general population. The 2004 National Immunization Coverage Survey (NICS) estimates that 94% of two year-olds have received one dose of measles vaccine and that 79% of seven year-olds have received at least two doses. Epidemiological and virological evidence suggests that endemic transmission of measles has been mostly interrupted since 1998; however, as expected, imported cases continue to occur. Secondary spread from these cases is usually self-limited and involves the few Canadians who are still vulnerable due to under-vaccination or opposition to immunization.

Over the past five years, there has been an average of 10 measles cases each year in Canada with clusters of approximately 4 cases. The last large outbreak happened in the year 2000. It was centered in Alberta and involved nearly 200 individuals; nearly all of them un-immunized for religious or philosophical reasons. The initial cases were imported from Mexico and Bolivia.
Mumps

Mumps is an acute infectious disease caused by mumps virus. About 40% of those infected develop acute parotitis, which is unilateral in about 25% of cases. Nonspecific or primarily respiratory symptoms occur in about half of those who acquire infection. Subclinical infection is common. Although complications are relatively frequent, permanent sequelae are rare. Before the widespread use of mumps vaccine, mumps was a major cause of viral meningitis.

Since the approval of vaccine in 1969, the number of reported mumps cases has decreased by greater than 99% from an average of 34,000 cases reported per year in the early 1950s to under 400 cases per year in the early 1990s. A further reduction in incidence was observed following the introduction of the routine second dose of MMR. The annual number of reported cases has continued to drop; during the period 2000-2004, an average of 87 cases were reported annually, ranging from 32 (2004) to 205 cases (2002).

Rubella

Rubella is a viral disease that results in a transient erythematous rash, post-auricular or suboccipital lymphadenopathy, arthralgia and low-grade fever. As symptoms are non-specific, it may be mistaken for infection due to parvovirus, adenoviruses or enteroviruses. Adult infection is frequently accompanied by transient polyarthralgia or polyarthritis. Serious complications are rare, and up to 50% of infections are subclinical.

The main goal of immunization is the prevention of rubella infection in pregnancy, which may give rise to congenital rubella syndrome (CRS). This syndrome can result in miscarriage, stillbirth and fetal malformations, including congenital heart disease, cataracts, deafness and mental retardation.

An MMR immunization program for all infants was introduced in Canada in April 1983. The average number of rubella cases reported decreased from approximately 5,300 (1971-1982) to fewer than 30 cases per year (1998-2004). The average annual incidence decreased from 0.08 per 100,000 in 1998 to 0.03 per 100,000 in 2004 (range: 0.02-0.09 per 100,000 per year).

Varicella

Varicella-zoster virus (VZV) is a DNA virus of the herpes virus family. VZV causes a primary illness (varicella or chickenpox) and establishes latency in the sensory nerve ganglia, which may be reactivated later as herpes zoster (shingles). VZV is spread by the airborne route as well as by direct contact with the virus shed from skin lesions.

Varicella has been considered to be a benign disease in otherwise healthy children aged up to 12 years. However, this group accounts for 80% to 85% of varicella-associated physician visits, 85% to 90% of hospitalizations and nearly 50% of fatal cases. The complications of chickenpox include secondary bacterial skin and soft tissue infections, otitis media, bacteremia, pneumonia, osteomyelitis, septic arthritis, endocarditis, necrotizing fasciitis, toxic shock-like syndrome, hepatitis, thrombocytopenia, cerebellar ataxia, stroke and encephalitis.
Varicella case fatality rates are highest among adults (30 deaths/100,000 cases), followed by infants under 1 year of age (7 deaths/100,000 cases) and then those aged 1 to 19 years (1-1.5 deaths/100,000 cases). Since 2000, a total of six pediatric deaths due to varicella were reported by the Immunization Monitoring Program ACTive (IMPACT) system, with a range of 0-3 deaths per year. In the pre-vaccine era in the United States, adults accounted for only 5% of cases but 55% of the approximately 100 chickenpox deaths each year. In Canada, 70% of the 59 chickenpox-related deaths in the pre-vaccine years (1987 to 1997) occurred in those over 15 years of age.

The total medical and societal costs of varicella in Canada were estimated in a multicentre study to be $122.4 million yearly or $353.00 per individual case. Eighty-one percent of this amount went toward personal expenses and productivity costs, 9% toward the cost of ambulatory medical care and 10% toward hospital-based medical care.

Benefits from varicella immunization have been seen in the United States after varicella vaccine was licensed in 1995. From 1995 to 2005, the United States recommended that children 12-18 months of age receive a single dose of varicella vaccine, with catch-up vaccination of older, susceptible children and adults. Varicella disease incidence in children 19-35 months old declined by 70%-85% in three U.S. communities that had achieved vaccine coverage levels of 75%-85%. Varicella-related hospitalizations in the United States decreased from 2.3-5 per 100,000 population in the pre-vaccine era (1993-1995) to 0.3-1.3 per 100,000 population in 2001-02. Ambulatory care visits for varicella also declined, by 59%. In 2000, the number of varicella-related deaths in the United States had declined by 78% in the < 20 year age group and by 63% in the 20-49 year age group, as compared with the pre-vaccine years, 1990-94.vii In 2007, the Advisory Committee on Immunization Practices in the United States recommended that children receive 2 doses of varicella vaccine at 12 months and 4-6 years of age (preschool) in order to help reduce the number of breakthrough cases that were being observed. 

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References:

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vii ibid
viii 2007 ACIP Recommendations on the prevention of Varicella