

**MINISTRY OF HEALTHY LIVING AND SPORT
INFORMATION BRIEFING DOCUMENT**

Cliff # 841615 / x ref 811796, 786458

PREPARED FOR: Honourable Ida Chong, Minister of Healthy Living and Sport;
Honourable Kevin Falcon, Minister of Health Services
-FOR INFORMATION

TITLE: Updated Information Regarding the Recent Approval of Menveo, a
Competing Meningococcal Disease Quadrivalent Vaccine

PURPOSE: To provide information concerning the recent Health Canada approval of a
second quadrivalent vaccine, Menveo - for the prevention of
meningococcal disease.

BACKGROUND:

In 2009, the Ministry of Healthy Living and Sport began to explore the feasibility of modifying British Columbia's (BC) grade 6 immunization program in the autumn of 2010 by replacing the monovalent vaccine currently used with a more expensive quadrivalent vaccine in order to improve protection against rarer forms of meningococcal disease. This program change could be implemented with either of two quadrivalent products -- a SanofiPasteur vaccine (Menactra), or a Novartis vaccine (Menveo) for which Health Canada licensing has recently been given. Please see BN 786458 and 811796 for full background.

DISCUSSION:

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The competing quadrivalent vaccine manufactured by Novartis (Menveo) was approved in the United States on February 19, 2010, and in the European Union on March 15, 2010. On May 21, 2010, Health Canada's Biologics and Genetic Therapies Directorate (BGTD) also approved the Menveo vaccine.

The BC Centre for Disease Control (BCCDC) had recommended that BC wait for the approval of Menveo by Health Canada so that BC could benefit from a competitive bid process. Now that Menveo has been approved, competition will likely improve the cost effectiveness of a quadrivalent vaccine against meningococcal disease.

Novartis' Menveo vaccine will be available in the third or fourth week of July and will be \$101.00 per dose on the private market.

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There is no current plan for a national competitive bid process, although at any time BC could approach Public Works and Government Services Canada (PWGSC) and ask them to initiate a competitive process, although entering this agreement means committing to a successful bidder.

The Maritime Provinces, Ontario and the Northwest Territories have recently agreed to use Menactra. Quebec has no plans to enter into a competitive bid process until 2013, and Alberta, Saskatchewan and Manitoba are currently reviewing options, but will not likely consider any quadrivalent meningococcal vaccine contract until 2011.

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FINANCIAL IMPLICATIONS: N/A

CONCLUSION:

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Program Contact (for content): Warren O'Briain, Executive Director, Communicable Disease and Addictions Prevention; Craig Thompson, Director – Immunization
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Date: June 21, 2010; revised August 6, 2010
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**MINISTRY OF HEALTH
INFORMATION BRIEFING DOCUMENT**

Cliff # 688181

PREPARED FOR: Gordon Macatee, Deputy Minister - FOR INFORMATION

TITLE: Recent Death from Invasive Meningococcal Disease (IMD) and implications for BC's Vaccine Program

PURPOSE: A 15-year old child recently died from a strain of meningococcal disease not covered by BC's current vaccine program.

BACKGROUND:

On April 4, 2007, BC released *ImmunizeBC: A Strategic Framework for Immunization in BC* to stimulate collective action across the system to ensure British Columbians benefit from the many vaccines now available and understand the importance of immunizations for themselves, their families and vulnerable populations. BC's immunization program provides protection against 14 infectious diseases, including a infant and school-based vaccination program for meningococcal disease type C.

On April 24, 2007, a 15-year old boy died from a meningococcal type Y infection. There are 5 types of meningococcal bacteria causing invasive disease — A, B, C, W-135 and Y. To date, the most common forms seen in Canada have been the "B" and "C" types. Other serogroups account for about 1 case per 400,000 persons per year.

Type Y has recently become vaccine preventable by a newly available vaccine, Menactra™, which also provides immunity for the A, C and W-135 types. There is no vaccine available for the B type. Sanofi-Pasteur has strongly marketed Menactra™. The Meningitis Research Foundation of Canada, an advocacy group with industry ties, has put out a press release calling for Menactra™ to be available for all children in Canada. PEI is the only Canadian province offering Menactra™ through a school based, grade nine program.

DISCUSSION:

BC has historically seen between 30-50 cases of invasive meningococcal disease per year. Of these, about five to eight cases are from the A, Y or W-135 strains, which can occur at any age. In 2000, type C was the most common, but by 2006, the number of cases fell to four. Notable declines in children and teenagers are likely attributable to BC's current immunization program.

In the 11 years from 1996 to 2006, 42 out of 340 individuals infected with invasive meningococcal disease died: 28 from type C, 9 from type B, 3 from type Y and 2 from strains that could not be typed. The Y strain causes about one death per ten million people annually.

Currently, vaccines commonly used provide excellent protection and have a very good safety record. BC's vaccination program provides immunization for the C type at 2 and 12 months of age, and in grade 6. A catch-up program was also provided in 2004/05 and 2005/06 for grade 9 students and in 2005/06 and 2006/07 for grade 12 students.

Menactra™ has not been approved by Health Canada or the FDA (United States) for use in children under 2 years of age, so it cannot be used in BC's current 2 and 12 month infant program.

In December 2006, the Communicable Disease Policy Advisory Committee recommended the use of Menactra™ to those with specific medical conditions that place them at higher risk for invasive meningococcal disease and to close contacts of cases infected with type A, Y, or W-135 (Notably, the vaccine is being offered to close contacts of the recent case).

Canada's National Advisory Committee on Immunization (NACI) published its statement on this vaccine in May 2007. Due to current epidemiology of invasive meningococcal disease and concerns around a heightened risk of Guillain-Barré syndrome (roughly one case per million doses), NACI did not support routine use of Menactra™ in Canadian jurisdictions. However, NACI has recommended it for those aged 2-55 years who are at high risk, specifically travellers to areas where the vaccine is required, including pilgrims to the Hajj in Mecca; lab workers, and people with certain medical conditions.

Menactra™ is considerably higher in cost compared with the present meningococcal C conjugate vaccine now provided in BC.

CONCLUSION:

British Columbia's current vaccine program provides protection for children starting at two months of age. Menactra is not approved for those less than two years of age. Consistent with the recommendation of NACI, Menactra is being provided to individuals identified as high risk. Public health experts will continue to monitor the epidemiology of meningococcal disease and will make recommendations if the science supports a change to our current vaccine program.

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Date:	May 7, 2007
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**MINISTRY OF HEALTH
INFORMATION BRIEFING DOCUMENT**

Cliff# 890051

PREPARED FOR: Honourable Michael de Jong, Minister - **FOR INFORMATION**

TITLE: Updated Information Regarding Meningococcal Vaccines

PURPOSE: To provide information concerning meningococcal vaccines.

BACKGROUND:

- British Columbia presently offers publicly funded vaccine as part of the routine childhood vaccination program and adolescent (grade 6) vaccination program
- The meningococcal vaccine program was initiated in 2003 to protect against the most common strain preventable by vaccine – meningococcal C.
- There are 5 strains of meningococcal disease (C, A, B, Y & W-135):
 - Meningococcal C disease is now rare because of the vaccine program for infants and school age children;
 - Meningococcal A strain is not endemic in North America at this time;
 - Meningococcal B strain is now the most common strain – in 2009, 16 out of 23 meningococcal disease reports in British Columbia were meningococcal B;
 - The concentration of meningococcal B cases is in infancy while the median age of meningococcal Y and W-135 cases is mid-adulthood.
- There are two meningococcal quadrivalent vaccines on the market, Menactra® (a Sanofi Pasteur product) and the recently approved Novartis product called Menveo®.
- Both products offer protection against four strains of meningococcal disease (A, C, W-135 & Y), but do *not* provide coverage for the B strain.
- The Menactra® manufacturer is lobbying BC for universal use of its vaccine.
- Ontario, New Brunswick, Newfoundland, Alberta, Saskatchewan, and the Northern Territory (NT) (only to post-secondary students outside the NT) offer Menactra® as a school based adolescent booster dose.
- In these school-based programs, Menactra® replaced the group C vaccine. It did not replace the infant meningococcal C program because Menactra® is not approved for use in children under two years of age.
- Menactra® has been considered for use in BC for several years, with periodic reviewed by the Communicable Disease Policy Committee chaired by Dr. Perry Kendall, Provincial Health Officer. It was most recently considered at the May 2011 meeting of the committee along with immunization programs against eight other diseases.
- The incremental cost effectiveness of a meningococcal quadrivalent vaccine program is high, and above the generally accepted threshold of about \$40,000 per quality adjusted life year gained for introduction of new vaccines.
- New information about Menactra® emerging from use in the USA is the need for periodic booster doses to maintain protection. Booster doses are now recommended by the US Advisory Committee on Immunization for healthy adolescents who were immunized at 11 years of age to be given five years later. This doubles the cost of a program and makes it less cost effective.

- With the mid-adult median age of the two additional serogroups against which protection would be obtained with a quadrivalent vaccine, immunization would have to continue for many years to result in appreciable reductions in disease.
- At its July 2011 meeting, the Communicable Disease Policy Committee recommended priority introduction of three other vaccine programs: rotavirus for infants, varicella 2nd dose for children, and hepatitis A for aboriginal children. These are all deemed a higher priority than a quadrivalent meningococcal vaccine program.
- A new vaccine against the meningococcal B strain is expected to be approved by Health Canada before the end of 2011. This vaccine will be considered a high priority for consideration by the Communicable Disease Policy Committee because the disease burden is far higher than for groups Y and W-135 and a childhood immunization strategy could potentially result in large reductions.

DISCUSSION:

- With the median age of meningococcal Y and W-135 cases in mid-adulthood, an ideal vaccine for optimum protection has not been developed.
- Recent data on Menactra® from the US experience is that immunity wanes over time and they now recommend immunization at age 11 with a booster dose 5 years later.
- It is not yet known whether the booster dose of Menactra® will provide sustained protection which could mean that adults will need periodic booster doses.
- The BC Centre for Disease Control (BCCDC) will continue to support scientific review of the basis for new or expanded immunization programs by the Communicable Disease Policy Committee, including assessing a new vaccine against the most prevalent strain (B) if approved by Health Canada later this year.

FINANCIAL IMPLICATIONS:

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CONCLUSION:

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**MINISTRY OF HEALTHY LIVING AND SPORT
INFORMATION BRIEFING DOCUMENT**

Cliff # 832794/ x ref 811796

PREPARED FOR: Honourable Ida Chong, Minister of Healthy Living and Sport;
Honourable Kevin Falcon, Minister of Health Services
-FOR INFORMATION

TITLE: Updated Information Regarding competing Meningococcal Disease
Quadrivalent Vaccines (Menactra and Menveo)

PURPOSE: To provide an update concerning quadrivalent vaccines - SanofiPasteur
Menactra vaccine and a soon to be approved competing vaccine by
Novartis' Menveo vaccine for the prevention of meningococcal disease.

BACKGROUND:

In September 2009, a decision was made to explore the feasibility of modifying British Columbia's (BC) grade 6 immunization program in the autumn of 2010 by replacing the monovalent vaccine currently used with a more expensive quadravalent vaccine in order to improve protection against rarer forms of meningococcal disease. It is expected that this program change could be implemented with either of two quadravalent products -- a SanofiPasteur vaccine (Menactra) that is currently approved for use in Canada, or a Novartis vaccine (Menveo) for which federal licensing is expected at the end of May 2010. Please see BN 786458 and 811796 for full background.

DISCUSSION:

SanofiPasteur has been meeting with provincial health ministers across Canada to advocate that provinces shift from monovalent vaccine to Menactra. SanofiPasteur has invited family members of adolescents, who have died from meningococcal disease, to accompany the manufacturer in meetings with provincial ministers. SanofiPasteur met with Minister Chong on July 27, 2009.

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The competing quadrivalent vaccine manufactured by Novartis (Menveo) was approved in the United States on February 19, 2010, and in the European Union on March 15, 2010. As of May 5, 2010, BCCDC has been notified that Biologics and Genetic Therapies Directorate (BGTD) is finalizing the product monograph (e.g. including stability information in the Product Monograph). It is expected that approval of Menveo by Biologics and Genetic Therapies Directorate (BGTD) will occur by the end of May 2010.

BCCDC has recommended that BC wait for the approval of Menveo by Health Canada and enter into competitive bid process, prior to announcing a publicly funded meningococcal quadrivalent immunization program. A lower price through competition would improve the cost effectiveness of a quadravalent vaccine against meningococcal disease.

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FINANCIAL IMPLICATIONS: N/A

CONCLUSION:

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BRIEFING RECOMMENDED:

Yes ☐ No ☒

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**MINISTRY OF HEALTHY LIVING AND SPORT
DECISION BRIEFING DOCUMENT**

Cliff # 786458

PREPARED FOR: Ida Chong, Minister, Healthy Living & Sport - **FOR DECISION**

TITLE: Menactra Vaccine and Immunizing Against Meningococcal Disease in British Columbia (BC)

PURPOSE: To inform a decision regarding the possible use of Menactra vaccine or another quadravalent product in BC's grade six immunization program.

BACKGROUND:

Infection from meningococcus bacteria can result in serious meningococcal disease, including bacterial meningitis (an inflammation of the tissue surrounding the brain and spinal cord) and meningococcemia (a widespread infection of the blood and other organs). Between January 1, 2004 and July 6, 2009, BC has recorded 133 cases of meningococcal disease, of which 17 proved fatal.

There are five common strains of meningococcal disease: A, B, C, Y and W135. Strains B and C account for the majority of cases in BC and Canada. The meningococcal vaccine currently used in BC (meningococcal C conjugate) protects against the 'C' strain only and is offered at two and 12 months of age as recommended by the National Advisory Committee on Immunization (NACI). In addition, BC offers meningococcal C conjugate to grade six students as part of a catch-up program. This catch-up program was to end this year but recently NACI added a recommendation for a booster shot in grade six, in addition to the scheduled two and 12 month doses. Beginning this fall BC's grade 6 meningococcal catch-up program will be replaced with a booster program.

Menactra vaccine is a quadrivalent meningococcal vaccine. A quadrivalent vaccine protects against four strains of the same disease. Menactra vaccine, manufactured by Sanofi Pasteur, protects against the following four strains of meningococcal disease: A, C, Y and W135. Both Menactra and meningococcal C conjugate protect against the 'C' strain. The three additional strains of meningococcal disease (A, Y, W135) that Menactra vaccine offers protection against are quite rare in BC.¹ There is currently no vaccine available in Canada for the 'B' strain.

Menactra vaccine has not been approved by Health Canada for children less than two years of age. Therefore, notwithstanding the introduction of Menactra vaccine, BC must continue immunizing infants at 2 months and 12 months of age with meningococcal C conjugate vaccine.

¹ See Appendix A

Previously, the BC Centre for Disease Control (BCCDC) and the Office of the Provincial Health Officer (PHO) recommended against the use of quadravalent Menactra vaccine for the grade six program due to the rarity of the 3-meningococcal strains in question and the significant increased cost of Menactra vaccine. NACI recommended the choice of vaccine be determined by individual provinces based on their own assessment of epidemiological evidence, but did indicate that Menactra vaccine is a better choice for prevention with vulnerable and high risk populations. BC is following this recommendation and is publicly funding Menactra vaccine for vulnerable and high risk populations, as they are more susceptible to the rare strains of meningococcal disease.

There is inconsistent use of Menactra vaccine across the country. Currently, Prince Edward Island and New Brunswick are the only provinces using Menactra vaccine in a routine school immunization program (grade 9) and Ontario is the only other province to publicly announce that it would offer Menactra vaccine to students (grade seven) beginning in the fall of 2009.

DISCUSSION:

NACI recently updated its recommendations for meningococcal disease immunization by suggesting a single dose meningococcal booster shot be given around grade six. The NACI has indicated that selecting a particular vaccine is at the discretion of the provinces and territories.

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² See Appendix A

Sanofi-Pasteur has been aggressively marketing Menactra given another meningococcal quadrivalent vaccine, from Novartis, is expected to receive Health Canada approval later this year. The introduction of another quadravalent vaccine into the Canadian market will likely force a competitive bid process that should result in a reduction in price of both vaccines, allowing for a more cost-effective introduction of a quadrivalent meningococcal vaccine, whether it is Menactra or the other product from Novartis.

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RECOMMENDATION.

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Approved/Not Approved
Ida Chong, FCGA
Minister

Date Signed

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CDAP September 8.doc

Appendix A

BC's meningococcal morbidity and mortality rates (2004 - present)³

Year		A	B	C	W-135	Y	A+Y+W135
2004	SURVIVED		3	12		1	1
2004	DIED			7			0
2004	UNKNOWN		4	2	1		1
2005	SURVIVED		4	5	3	3	6
2005	DIED		1	2			0
2005	UNKNOWN		3	2	1	4	5
2006	SURVIVED	2	5	3		4	6
2006	DIED			1		1	1
2006	UNKNOWN		1				0
2007	SURVIVED		9	4	2	7	9
2007	DIED					1	1
2007	UNKNOWN		2	3			0
2008	SURVIVED		5	7		3	3
2008	DIED			3			0
2008	UNKNOWN					1	1
2009 (Jul 6)	SURVIVED		7	1		2	2
2009 (Jul 6)	DIED					1	1
Total number of cases		2	44	52	7	28	37

Since 2004 there have been 3 deaths related to A, Y, or W135 strains.

Since 2004 there have been 13 deaths related to C strain.

Since 2004 there has been 1 death related to B strain.

³ Adapted from BCCDC's, "Meningo-Serogroup Outcomes" July 2009.