ProQuad[™] - Measles, Mumps, Rubella and Varicella (MMRV) Vaccine Questions and Answers for Immunization Providers – April 2014

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1. When was ProQuad™ authorized for use in Canada?

 $ProQuad^{TM}$, manufactured by Merck Canada Inc., was approved for use by Health Canada in 2012. 1

2. What is the intended use of the ProQuad™ vaccine in BC?

In January 2012 the second dose of MMR was moved from 18 months to 4-6 years (school entry) in the BC routine immunization schedule. Children who were 18 months of age on or after January 2012, and who will be turning 4 beginning July 2014, should be offered the combination MMRV vaccine (ProQuadTM).

Separate MMR and varicella vaccines will continue to be available in BC for children who do not require a 2nd dose of both MMR and varicella vaccines at school entry or who have a contraindication to the combination product. As well as for use at 12 months of age, when the 1st doses of MMR and varicella vaccines are administered.

Limited quantities of this product will be available for use in children 7-12 years of age who require protection against measles, mumps, rubella and varicella such as those delayed for their school entry booster dose.

3. Who may receive ProQuad™ vaccine?

The eligible groups for this vaccine are listed under 'Indications' within the <u>BC Immunization</u> Manual, Section VII page 36a.

- School entry booster (4-6 years of age)
- Susceptible unimmunized or incompletely immunized persons 4-12 years of age^A

There are no priority groups within the eligible population as immunization against these 4 diseases is routinely recommended for all children except those with contraindications to receipt of these vaccines.

4. Who should not receive MMRV vaccine?

Persons with impaired immune function due to disease or therapy, including primary or secondary immunodeficiency disorders, should not receive combination MMRV vaccines. Such individuals should be offered MMR and varicella vaccines by separate injection if indicated as per <u>Special Populations Section III-Immunization of Special Populations</u>, <u>Subsection 1.0 Immunocompromised Individuals</u>. See also separate MMR and varicella vaccine product pages.

5. How is ProQuad™ supplied?

ProQuad[™] is supplied as a 0.5 mL single dose vial of lyophilized vaccine to be reconstituted using the sterile diluent supplied. Use only the diluent supplied because it is free of preservatives or other antiviral substances, which might inactive the vaccine viruses. ³

6. Are there any specific administration considerations?

- a) After reconstitution, the entire contents of the vial should then be withdrawn and administered. None of the reconstituted product should be left in the vial. The volume of reconstituted vaccine for ProQuadTM will be **approximately** 0.7mL and this entire volume should be administered.
- b) This vaccine should be administered via the subcutaneous (SC) route **only**.
- c) Although the product monograph allows for reconstitution up to 30 minutes prior to administration, pre-drawing vaccine, as a routine practice, is **not** recommended.

A varicella susceptible person is one without a history of varicella or herpes zoster after 12 months of age and without a history of age appropriate varicella immunization. A self reported history of varicella is adequate for those born before 2004; for those born in 2004 and later, a health care provider diagnosed history is required for reliability. Children who have a history of either physician diagnosed herpes zoster or lab-confirmed varicella after their 1st dose do not require a 2nd dose as they will have developed immunity. If disease history is uncertain, provide a 2nd dose.

7. Why are we not administering MMRV vaccine at 12 months of age?

Administration of MMRV vaccine to children 12 to 23 months of age (dose 1) has been associated with an approximate two-fold increase in the risk of febrile seizures 5 to 12 days after vaccination when compared to children vaccinated with MMR and varicella separately.³ This risk would translate to about 20 excess febrile seizures each year in 1 year old children in BC (approximately 1 per 2 600 vaccinees⁴). **This risk is not seen within the 4-6 year of age group** as areas of the brain thought to be involved in febrile seizures have matured. For this reason, the BC Communicable Disease Policy Advisory Committee concluded that separate MMR and varicella vaccines are preferable at 12 months of age (dose 1).

8. Can you tell me more about the risk of febrile seizures?

Febrile seizures in young children are common and generally benign. Febrile seizures are reported in 2% to 5% of children between the ages of 3 months and 5 years. They are commonly caused by fevers secondary to childhood illnesses (e.g., middle-ear infections, viral upper respiratory tract infections, and roseola) but can be associated with any condition that results in fever, including vaccination.

Please direct interested parents to <u>HealthLinkBC's file #112 - Febrile Seizures</u> for more information.

REFERENCES:

¹ Notice of Compliance Search: ProQuad. Public Health Agency of Canada. Available from http://webprod5.hc-sc.gc.ca/noc-ac/search-recherche.do?lang=eng

² Merck Sharp & Dohme Corporation. 2014. ProQuad: Highlights of Prescribing Information. Available from http://www.merck.com/product/usa/pi_circulars/p/proquad/proquad_pi.pdf

³ Merck Canada Inc. Product Monograph ProQuad®. Kirkland (QC): 2012.

⁴ MMRV safety studies. Vaccine Safety Datalink. Available from http://www.cdc.gov/vaccinesafety/vaccines/mmrv/studies.html

⁵ National Advisory Committee on Immunization. Statement on measles-mumps-rubella-varicella vaccine. *Canada Communicable Disease Report (CCDR).* 2010; 36(ACS-9):1-22.

⁶ Advisory Committee on Immunization Practices. Centres for Disease Control and Prevention. Use of Combination Measles, Mumps, Rubella, and Varicella Vaccine. *Morbidity and Mortality Weekly Report (MMWR)*. Recommendations and Reports. 2010; 59(RR03):1-12. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5903a1.htm