

Saskatchewan Immunization Manual Amendments April 2022

Instructions: Please remove and discard the corresponding pages in each chapter section as applicable and insert the amended pages as noted below in each corresponding chapter section.

Chapter 9 – Management of Biological Products

- Revised TOC second page as Appendix 9.2 has been added.
- Page 10 Section 2.5.3 Temperature Indicator Cards
 - States to refer to Appendix 9.2
- **New!** Appendix 9.2 Temperature Indicator Information Sheet
 - Added for staff reference.
 - It is suggested to have a printed version in each area where vaccine shipments are unpacked.

Chapter 10 Biological Products

- Janssen
 - Updated product monograph March 24/22
 - Under Contraindications: TTS
 - New bullets:
 - Individuals who have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with adenovirus-vectored COVID-19 vaccine should not receive Janssen COVID-19 vaccine. A combination of thrombosis and thrombocytopenia, including TTS, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Janssen COVID-19 Vaccine during post-authorization use. This includes severe cases at unusual sites such as cerebral venous sinus thrombosis (CVST) and splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of cases occurred within three weeks following vaccination.
 - Cases of TTS following administration of the Janssen COVID-19 Vaccine have been reported in individuals, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30-49 years; overall, approximately 15% of TTS cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia (HIT). Currently available evidence supports a causal relationship between TTS and the Janssen COVID-19 Vaccine.
 - Under Possible Reactions, new additions:
 - Malaise, asthenia, muscular weakness, pain in extremities, paresthesia, hypohesia, dizziness, diarrhea and vomiting; tinnitus; transverse myelitis.