SASKATCHEWAN COLLEGE OF PHARMACY PROFESSIONALS

Status Update – COVID-19 Rapid Antigen Tests in Pharmacies

The regulations around COVID-19 testing have seen many changes over the past year and SCPP would like to provide guidance to members of the following provisions that are in force based on our information as of **Mar. 11, 2024**.

Disclaimer

Although reference is being made to specific sections for further clarity, the terms, conditions and standards in the following SCPP documents must be taken together as a whole when referring to authorized practices under Part M of the SCPP Regulatory Bylaws: Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting, the Sale and Distribution of Medical Testing Devices and Other Diagnostic Products, and Performing Tests for Drug Therapy Management. It is strongly recommended that pharmacists familiarize themselves with these requirements before participating in any testing activities to ensure that they are practising within the scope and standards of practice required to maintain public safety, as well meeting statutory obligations with respect to their license and malpractice insurance.

Practice Area	Tests Authorized	Description	Authorization
Selling COVID-19 Self-Tests **(NB "selling" and "distributing" are not the same and have different terms and conditions.)**	Health Canada approved COVID-19 "**self-testing" devices**. See here for Health Canada's list of approved COVID-19 Self-Testing Devices.	Must be approved for "self-testing", by Health Canada. Intended user is the general public to perform testing for personal use independent of a health care worker. Note: devices approved for "self-collection" or "self-collection under supervision of a health care worker" are **point-of care testing devices (POCT).** (See "Performing" section below.)	**SCPP** For more information on SCPP terms, conditions and standards see: • Laboratory Tests and Medical Devices – Accessing, Ordering, Performing, Using, or Interpreting (Appendix D) • Sale and Distribution of Medical Testing Devices and Other Diagnostic Products. Medical testing devices approved for self-testing may be sold in the pharmacy. (See section 2 for SCPP standards).

Practice Area	Tests Authorized	Description	Authorization
		For more information on the difference between “POCT” and “self-tests” (also known as “patient-administered tests”) see here.	Note: Pharmacies are not permitted to sell to the general public: • Point-of-care tests; • Any rapid antigen tests distributed through federal/provincial publicly funded; or • Serological (antibody) testing devices.
Distributing Point-of-Care Tests to Businesses for Occupational Health & Safety (also known as “Test to Protect” and the federal SME program) (Federal/Provincial Publicly Funded) This workplace screening initiative is no longer underway.	Rapid Antigen POCT supplied through federal/provincial workplace screening programs Point of Care Tests no longer available for this initiative.	**Occupational health and safety purposes only.** Workplace screening to help businesses detect early cases of COVID-19, for people who are asymptomatic.	**SCPP** All distribution from, or through a pharmacy, must comply with the terms, conditions, wand standards of the SCPP, see: • Laboratory Tests and Medical Devices – Accessing, Ordering, Performing, Using, or Interpreting; and • Sale and Distribution of Medical Testing Devices and Other Diagnostic Products. Any POCT **distributed** by a pharmacy must be done in conjunction with a third party that is authorized to do so under applicable legislation when needed, (section 2.3) and is doing so in accordance with the terms and conditions set (see section 2.13 for the federal/provincial publicly funded programs).

Practice Area	Tests Authorized	Description	Authorization
			Federal/Provincial Governments ***Federal*** Interim enforcement order in effect until Dec. 31, 2024 permits (see here for details): • Distribution to businesses without a Medical Device Establishment Licence (MDEL); and • See here for most current Medical Device Compliance Program bulletins. • See here for Provincial/ Territorial Resources. ***Provincial*** Amendments to *The Medical Laboratory Licensing Regulations* to permit POCT COVID-19 Rapid Antigen testing to occur in locations outside of a medical laboratory. (See SK Opens up Access to Rapid Antigen Tests (June 10, 2021). • See here for Saskatchewan Testing & Treatment Information.