

Policy Title	Health Canada Special Access Programme (SAP) Requests
Revision Date(s)	September 25, 2023
Effective Date	October 23, 2023
Approving Body	Provincial RITHIM Committee
Responsible Officer	Director, RITHIM

## 1 PURPOSE

The purpose of this policy is to define the Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) requirement for ethical review of Health Canada Special Access Programme (SAP) requests.

## 2 DEFINITIONS

Health Canada Special Access Programme (SAP): allows practitioners to submit a request to Health Canada for access to a drug that is unavailable for sale in Canada. This access is limited to provision to patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable. The SAP is not intended to be a mechanism to promote or encourage the early use of drugs or to circumvent the clinical trials review and approval process or the new drug approval process, but rather to provide compassionate access to drugs on a patient-by-patient basis for clinical reasons not related to research.

## 3 POLICY

Submission to CHIPER for review and approval in SAP circumstances is not required. If an application relating to SAP is submitted, it will not be reviewed by CHIPER.

## 4 PROCEDURES

Regulatory requirements regarding approval, provision, consent, documentation, and record-keeping should be obtained from and maintained directly with the Health Canada Special Access Programme (SAP). A practitioner who has obtained Health Canada SAP approval is required to comply with Health Canada SAP regulations, as well as any related institutional requirements.