

# MAKING URGENTLY NEEDED DRUGS AVAILABLE

## Responding to the Opioid Crisis and Other Emergency Situations



### EXISTING | EMERGENCY MECHANISMS TO ACCESS DRUGS

#### SPECIAL ACCESS PROGRAMME

#### INTERIM ORDER



### NEW | MECHANISM TO ACCESS DRUGS TO MEET AN URGENT PUBLIC HEALTH NEED

#### ACCESS TO DRUGS IN EXCEPTIONAL CIRCUMSTANCES REGULATIONS

#### WHAT ARE THE MECHANISMS?

- Provides access to unapproved drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable or are unavailable.

- Provides the Minister of Health with authority to initiate immediate action to deal with a significant risk to health, safety or the environment.

- Provides regulations to import foreign authorized drugs, not approved in Canada, that would help address an urgent public health need.
- These drugs are authorized for sale in the United States, the European Union or Switzerland.

#### WHO REQUESTS ACCESS TO THE DRUGS?

- Practitioner (Physician).

- Minister of Health.

- Federal, Provincial or Territorial public health official.

#### WHAT'S THE TARGET POPULATION?

- Individual patients.

- General population of Canada.

- Population under the public health official's authority.

#### WHAT'S THE PROCESS TO ACCESS DRUGS?

- Application from practitioner on behalf of a patient.
- Application is reviewed by Health Canada.

- Requires Governor in Council approval.

- Streamlined notification by a public health official to Health Canada.

#### WHEN CAN IMPORTED DRUGS BE USED?

- As deemed by practitioner.

- Immediately.

- Immediately.

#### HOW LONG WILL ACCESS TO DRUGS BE GRANTED?

- Time limited. Practitioner-based process for renewal of additional quantities.
- Subsequent authorization is needed to treat additional patients.

- One year.

- One year. Renewable based on the urgent public health need.

#### WHAT ABOUT SECURITY?

- Any drug that is a controlled substance continues to be subject to the requirements of the *Controlled Drugs and Substances Act*.