Member's Bill

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Legislative Assembly of British Columbia

BILL M ___

PHARMACEUTICAL RISK MANAGEMENT AND ACCOUNTABILITY ACT

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Explanatory Note

This Bill provides for classes of drugs to be designated as experimental drugs classes and requires that practitioners not prescribe, dispense or administer a drug in an experimental drugs class unless the wholesaler of the drug has entered into a risk management agreement that includes

- a requirement that the wholesaler establish and administer a compensation fund for payments to affected patients, and
- a requirement that the wholesaler indemnify the government for certain health care system costs.

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HIS MAJESTY, by and with the advice and consent of the Legislative Assembly of the Province of British Columbia, enacts as follows:

Definitions

1 In this Act:

"drug" has the same meaning as in the *Pharmacy Operations and Drug Scheduling Act*;

"experimental drugs class" means a class of drugs that has been designated under section 2;

"harm reduction program" means overdose prevention services, including the support and monitoring of persons who consume drugs, provided primarily in the community, at residential facilities or on premises used to provide public health interventions, including sites commonly known as safe consumption sites;

"practitioner" has the same meaning as in the *Pharmacy Operations and Drug Scheduling Act*;

"risk management agreement" means an agreement described in section 3 (1) (a);

"wholesaler" has the same meaning as in the *Pharmacy Operations and Drug Scheduling Act*.

Designation as experimental drugs class

2 (1) The following classes of drugs are designated as experimental drugs classes:

(a) messenger RNA vaccines and other vaccines that are dispensed or administered as part of the Province's immunization program against COVID-19;

(b) classes of drugs that are prescribed, dispensed or administered as part of a harm reduction or safer supply program;

(c) classes of drugs that are prescribed, dispensed or administered to suppress puberty or to provide other hormone treatment for the purpose of gender transition;

(d) selective serotonin reuptake inhibitors that are prescribed, dispensed or administered for mental health purposes.

(2) The minister may designate additional classes of drugs as experimental drugs classes.

(3) In determining whether to make a designation under subsection (2), the minister may consider one or more of the following:

(a) the prevalence throughout the province of the use of drugs in the class of drugs;

(b) the generally accepted degree of uncertainty respecting the long-term effectiveness of drugs in the class of drugs on patients to whom the drugs are administered for the relevant purpose set out in this section;

(c) the generally accepted degree of uncertainty respecting the long-term safety of the use of the drugs in the class of drugs by patients to whom the drugs are administered for the relevant purpose set out in this section;

(d) the potential for significant health care system costs associated with

(i) adverse health impacts on patients,

(ii) long-term patient outcomes, or

(iii) increased use of publicly funded health services,

related to the use of drugs in the class of drugs;

(e) any other factor the minister considers relevant to public health.

Conditions for prescribing, dispensing and administering drugs in experimental drugs classes

3 (1) A practitioner must not prescribe, dispense or administer a drug that is in an experimental drugs class unless

(a) the wholesaler of the drug has entered into a risk management agreement that is in the prescribed form, is satisfactory to the minister and contains the following provisions:

(i) a requirement that the wholesaler establish and administer a compensation fund for payments to patients who have experienced, or are at material risk of experiencing, adverse health impacts or related burdens associated with the use of the drug;

(ii) a requirement that the wholesaler indemnify the government for any health care system costs associated with

(A) adverse health impacts on patients,

(B) long-term patient outcomes, or

(C) increased use of publicly funded health services,

related to the use of drugs in the class of drugs;

(iii) other prescribed content, and

(b) the drug is prescribed, dispensed or administered in accordance with conditions established by the minister under subsection (2).

(2) The minister may establish conditions for the purposes of subsection (1) (b), including conditions respecting

(a) the monitoring and reporting by the wholesaler to the minister on the prescribing, dispensing and administering of the drug, and

(b) any other matter the minister considers necessary for the protection of public health.

Conditions for public funding for use of drugs in experimental drugs class

4 (1) The minister may require the wholesaler of a drug that is in an experimental drugs class to enter into a risk management agreement as a condition of

(a) inclusion of the drug in a publicly funded health program, or

(b) participation in a publicly administered health protection initiative.

(2) The conditions established by the minister under section 3 (2) apply to the prescribing, dispensing and administering, in a health care facility or class of health care facilities licensed or regulated under an Act, of a drug that is in an experimental drugs class.

Regulations

5 (1) The Lieutenant Governor in Council may make regulations referred to in section 41 of the *Interpretation Act*.

(2) Without limiting subsection (1), the Lieutenant Governor in Council may make regulations respecting the form and content of risk management agreements.

Conflicts

6 To the extent of any conflict with a provision of another enactment, this Act prevails.

Commencement

7 This Act comes into force by regulation of the Lieutenant Governor in Council.