Exhibit R25-5 **Regulation SOR/2024-238 sections 24-40, which on November 29, 2024, amended the Food and Drug Regulations. The main change was to replace the term designated COVID-19 drug with the term public health emergency drug.**

Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Agile Licensing): SOR/2024-238

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FOOD AND DRUGS ACT

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Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, makes the annexed *Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Agile Licensing)* under section 30 [a] of the *Food and Drugs Act* [b].

Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Agile Licensing)

Food and Drug Regulations

1 Subsection A.01.015(2) of the *Food and Drug Regulations* [1] is replaced by the following:

(2) The adequate directions for use required to be shown on the inner and outer labels of a drug under subparagraph C.01.004(1)(c)(iii) or paragraph C.04.009(2)(f) shall be in English and French if the drug is available for sale without prescription in an open self-selection area.

2 Paragraph A.01.048(d) of the Regulations is replaced by the following:

(d) sections C.04.001 to C.04.006.

symbol “Pr” must be shown on

(a) the upper left quarter of the principal display panel of both the inner and the outer labels; or

(b) if the drug is packaged in a single-dose container, on the upper left quarter of the principal display panel of the outer label.

(2) Subsection (1) does not apply to a drug that is

(a) sold to a person who holds an establishment licence under Division 1A; or

(b) sold by a pharmacist under a prescription or by a practitioner, if its label shows suitable directions for use and meets the requirements set out in section C.01.005.

24 (1) The definition *designated COVID-19 drug* in section C.08.001.1 of the Regulations is repealed.

(2) Section C.08.001.1 of the Regulations is amended by adding the following in alphabetical order:

List of Conditions that Threaten Public Health
means the *List of Conditions that Threaten Public Health in Canada*, published on the Government of Canada’s website, as amended from time to time; (*Liste d’affections qui menacent la santé publique*)

public health emergency drug
means a new drug for which the purpose and conditions of use recommended by the manufacturer relate to a condition that is described in the List of Conditions that Threaten Public Health; (*drogue pour urgence de santé publique*)

25 The Regulations are amended by adding the following after section C.08.001.1:

C.08.001.2 (1) The Minister may add a condition to the List of Conditions that Threaten Public Health only if the Minister has reasonable grounds to believe that

(a) the condition presents, or is the result of, a significant risk to public health in Canada; and

(b) immediate action is required to deal with the risk.

(2) However, the Minister may add COVID-19 to the List of Conditions that Threaten Public Health, even if the criteria set out in subsection (1) are not met with respect to

COVID-19 at the time of the addition, as long as the Minister has reasonable grounds to believe that the addition is necessary to protect public health or safety.

C.08.001.3 If a condition that is on the List of Conditions that Threaten Public Health is removed from the list, a public health emergency drug that relates to that condition continues to be considered a public health emergency drug for the purposes of this Division if

(a) in respect of the public health emergency drug, a new drug submission has been filed under section C.08.002 or a supplement to a new drug submission has been filed under section C.08.003;

(b) the condition is removed from the List after the submission or supplement is filed; and

(c) the Minister has not issued, in respect of the submission or supplement, a notice of compliance under section C.08.004 or a notice under paragraph C.08.004(3)(b).

26 (1) Paragraph C.08.002(2)(o) of the Regulations is replaced by the following:

(o) in the case of a new drug for human use other than a public health emergency drug, an assessment as to whether there is a likelihood that the new drug will be mistaken for another drug for which a drug identification number has been assigned due to a resemblance between the brand name that is proposed to be used in respect of the new drug and the brand name, common name or proper name of the other drug.

(2) Subsection C.08.002(2) of the Regulations is amended by striking out "and" at the end of paragraph (n), by adding "and" at the end of paragraph (o) and by adding the following after paragraph (o):

(p) in the case of a new drug for human use, a risk management plan for the new drug that meets the requirements set out in section C.01.701, if

(i) there is a significant degree of uncertainty respecting the risks associated with the new drug, or

(ii) the new drug presents a serious risk of injury to human health that warrants that measures, other than labelling, be taken to reduce the probability or

severity of such an injury.

(3) Subsections C.08.002(2.1) to (2.3) of the Regulations are replaced by the following:

(2.01) If clinical trial data that is included in a new drug submission under paragraph (2)(g) or (h) or (2.1)(b) is broken down by population subgroup in an application made to the European Medicines Agency or the United States Food and Drug Administration to authorize the sale of the new drug, the data must be broken down in the same manner in the new drug submission.

(2.1) A manufacturer may file, for a public health emergency drug, a new drug submission that does not meet the requirements set out in paragraphs (2)(g) and (h) if the submission contains

(a) a statement that the submission contains evidence to establish that the requirement set out in paragraph (b) is met; and

(b) sufficient evidence to support the conclusion that the benefits associated with the public health emergency drug outweigh the risks associated with it for the purpose and under the conditions of use recommended, with consideration given to the uncertainties relating to those benefits and risks as well as the public health need related to the applicable condition described in the List of Conditions that Threaten Public Health.

(2.2) A manufacturer may file, for a public health emergency drug for human use, a new drug submission that does not meet the requirements set out in paragraph (2)(j.1) if the submission contains a draft of every label to be used in connection with the drug, including any package insert and any document provided on request that sets out supplementary information on the use of the drug.

(2.3) If, at the time a new drug submission is filed for a public health emergency drug, the manufacturer is unable to provide the Minister with information or material that is referred to in any of paragraphs (2)(e) to (k), (m) and (n) and (2.1)(b) and subsection (2.2) — and, as applicable, the corresponding material referred to in paragraphs C.08.005.1(1)(b) to (d) — or any of that information or material is incomplete, the manufacturer must provide the Minister, at that time, with a plan that specifies how and when they will provide the Minister with the missing information or

material.

(4) Subsection C.08.002(2.3) of the Regulations is replaced by the following:

(2.3) If, at the time a new drug submission is filed for a public health emergency drug, the manufacturer is unable to provide the Minister with information or material that is referred to in any of paragraphs (2)(e) to (k), (m), (n) and (p) and (2.1)(b) and subsection (2.2) — and, as applicable, the corresponding material referred to in paragraphs C.08.005.1(1)(b) to (d) — or any of that information or material is incomplete, the manufacturer must provide the Minister, at that time, with a plan that specifies how and when they will provide the Minister with the missing information or material.

(5) Subsections C.08.002(2.4) and (2.5) of the Regulations are replaced by the following:

(2.4) Subsections (2.1) to (2.3) apply only if

(a) the new drug submission contains a statement that the submission is for a public health emergency drug; and

(b) the purpose and conditions of use specified in the submission relate only to a condition described in the List of Conditions that Threaten Public Health and the submission contains a statement to that effect.

(2.5) Subsections (2.1) to (2.3) do not apply if a notice of compliance is being sought on the basis of a direct or indirect comparison between the new drug and another drug.

27 Paragraph C.08.002.01(2)(b) of the Regulations is amended by striking out "and" at the end of subparagraph (ix), by adding "and" at the end of subparagraph (x) and by adding the following after subparagraph (x):

(xi) a risk management plan for the new drug that meets the requirements set out in section C.01.701.

28 Subsection C.08.002.1(2) of the Regulations is amended by adding the following after paragraph (a):

(a.1) in the case of a new drug for human use, a risk management plan for the new drug that meets the requirements set out in section C.01.701, if one of the circumstances set out in subparagraphs C.08.002(2)(p)(i) and (ii) is met;

29 (1) Section C.08.003 of the Regulations is amended by adding the following after subsection (3):

(3.01) If clinical trial data that is included in a supplement to a new drug submission is broken down by population subgroup in an application made to the European Medicines Agency or the United States Food and Drug Administration to authorize the sale of the new drug, the data must be broken down in the same manner in the supplement.

(2) Section C.08.003 of the Regulations is amended by adding the following after subsection (3.1):

(3.2) A supplement to a submission referred to in subsection (1) for a new drug for human use shall contain

(a) if a risk management plan for the new drug has not yet been provided to the Minister and one of the circumstances set out in subparagraphs C.08.002(2)(p)(i) or (ii) is met, a risk management plan for the new drug that meets the requirements set out in C.01.701; or

(b) if there is already an *existing risk management plan* as defined in section C.01.700 and one of the circumstances set out in paragraphs C.01.703(a), (b) or C.01.704(1)(b) is met, an updated risk management plan for the new drug that meets the requirements set out in section C.01.701.

(3) Section C.08.003 of the Regulations is amended by adding the following after subsection (4):

(5) The manufacturer may file, for a public health emergency drug, a supplement to the new drug submission referred to in subsection (1) that does not contain all of the information and material that is required under subsection (3) if the supplement contains

(a) a statement that the supplement contains evidence to establish that the requirement set out in paragraph (b) is met; and

(b) with respect to the matters that are significantly different from those contained in the submission, sufficient evidence to support the conclusion that the benefits associated with the public health emergency drug outweigh the risks associated with it for the purpose and under the conditions of use recommended, with

consideration given to the uncertainties relating to those benefits and risks as well as the public health need related to the applicable condition described in the List of Conditions that Threaten Public Health.

(6) The manufacturer may file, for a public health emergency drug for human use, a supplement to the new drug submission referred to in subsection (1) that does not meet the requirements set out in subparagraph (3.1)(a)(ii) or (b)(ii) if the supplement contains a draft of every label to be used in connection with the drug, including any package insert and any document provided on request that sets out supplementary information on the use of the drug.

(7) If, at the time the manufacturer files, for a public health emergency drug, a supplement to the new drug submission referred to in subsection (1), the manufacturer is unable to provide the Minister with information or material that relates to any of the matters referred to in paragraphs (2)(d) to (h) and (5)(b) and subsection (6) — and, as applicable, the corresponding material referred to in paragraphs C.08.005.1(1)(b) to (d) — or if any of that information or material is incomplete, the manufacturer shall provide the Minister, at that time, with a plan that specifies how and when they will provide the Minister with the missing information or material.

(4) Subsection C.08.003(7) of the Regulations is replaced by the following:

(7) If, at the time the manufacturer files, for a public health emergency drug, a supplement to the new drug submission referred to in subsection (1), the manufacturer is unable to provide the Minister with information or material that relates to any of the matters referred to in paragraphs (2)(d) to (h), subsection (3.2), paragraph (5)(b) and subsection (6) — and, as applicable, the corresponding material referred to in paragraphs C.08.005.1(1)(b) to (d) — or if any of that information or material is incomplete, the manufacturer shall provide the Minister, at that time, with a plan that specifies how and when they will provide the Minister with the missing information or material.

(5) Section C.08.003 of the Regulations is amended by adding the following after subsection (7):

(8) Subsections (5) to (7) apply only if

(a) the supplement contains a statement that the supplement is for a public health emergency drug; and

(b) the purpose and conditions of use specified in the supplement relate only to a condition described in the List of Conditions that Threaten Public Health and the supplement contains a statement to that effect.

(9) Subsections (5) to (7) do not apply if a notice of compliance in respect of the supplement is being sought on the basis of a direct or indirect comparison between the new drug and another drug.

30 Section C.08.003.1 of the Regulations is replaced by the following:

C.08.003.1 In examining a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission or a supplement to any of those submissions, the Minister may, for the purpose of assessing the safety and effectiveness of the new drug for which the submission or supplement was filed, examine

(a) information or material provided by any person under the Act;

(b) information or material obtained from sites at which the new drug or any *active ingredient*, as defined in subsection C.01A.001(1), of the new drug is or is proposed to be *fabricated* or *packaged/labelled* within the meaning of those terms in that subsection, or tested; and

(c) information or material obtained directly or indirectly from a *foreign regulatory authority*, as defined in subsection C.10.001(1).

31 The Regulations are amended by adding the following after section C.08.003.1:

C.08.003.2 In cases where there are significant uncertainties respecting the evidence of the effectiveness of a new drug that was provided in a new drug submission or supplement to a new drug submission, the Minister may, in examining the submission or supplement, take into account whether terms and conditions that may be imposed or amended under section C.01.014.21 would enable the Minister to obtain additional information respecting the uncertainties if

(a) the new drug is intended to diagnose, treat, mitigate or prevent a disease, disorder or abnormal physical state, or symptom of a disease, disorder or abnormal

physical state, that poses or may pose a serious risk of injury to human or animal health; and

(b) either

(i) the recommended purpose and conditions of use of the new drug do not fall within the recommended purposes and conditions of use of any other drug for which a drug identification number has been assigned and not been cancelled, or

(ii) the recommended purpose and conditions of use of the new drug do fall within the recommended purposes and conditions of use of any other drug for which a drug identification number has been assigned and has not been cancelled, but the Minister has reasonable grounds to believe that the new drug is significantly more effective or poses a significantly lower risk than the other drug.

32 The Regulations are amended by adding the following after C.08.003.2:

C.08.003.3 For greater certainty, the obligation of the manufacturer to provide a risk management plan referred to in paragraph C.08.002(2)(p), subparagraph C.08.002.01(2)(b)(xi) or paragraph C.08.002.1(2)(a.1) or C.08.003(3.2)(a) or an updated risk management plan referred to in paragraph C.08.003(3.2)(b) may arise at any time before the Minister issues a notice of compliance under section C.08.004 or C.08.004.01 or a notice under paragraph C.08.004(3)(b) or C.08.004.01(3)(b).

33 The heading before section C.08.009.01 of the Regulations is replaced by the following:

Pre-positioning of Public Health Emergency Drugs

34 Section C.08.009.01 of the Regulations is amended by adding the following in alphabetical order:

dosage form class
has the same meaning as in subsection C.01A.001(1). (*classe de forme posologique*)

fabricate
has the same meaning as in subsection C.01A.001(1). (*manufacturer*)

package/label

has the same meaning as in subsection C.01A.001(1). (*emballer-étiqueter*)

35 Section C.08.009.02 of the Regulations is replaced by the following:

C.08.009.02 Sections C.08.009.03 to C.08.009.05 apply in respect of a public health emergency drug if

(a) a notice of compliance has not been issued in respect of the drug under section C.08.004 or C.08.004.01; and

(b) His Majesty in right of Canada has entered into a contract for the procurement of the drug.

36 Subsection C.08.009.03(1) of the Regulations is replaced by the following:

C.08.009.03 (1) The holder of an establishment licence may import a public health emergency drug if

(a) the Chief Public Health Officer provides the Minister with

(i) the name and contact information of the holder,

(ii) the name and contact information of the public health emergency drug's manufacturer,

(iii) the name of the public health emergency drug and a description of it,

(iv) information indicating that the public health emergency drug is the subject of a new drug submission, a supplement to a new drug submission or an application made to a foreign regulatory authority to authorize its sale,

(v) information specifying the quantity of the public health emergency drug to be imported, and

(vi) the civic address of the place where the public health emergency drug will be stored after it is imported;

(b) the holder provides the Minister with

(i) the name and contact information of each fabricator, packager/labeller and tester of the public health emergency drug and the civic address of each building at which the drug will be fabricated, packaged/labelled or tested, specifying for each building

(A) the activities referred to in Table I to section C.01A.008 that apply to the public health emergency drug,

(B) the categories referred to in Table II to that section that apply to the public health emergency drug, and

(C) for each of those categories, the dosage form classes, if any, and, in the case of a public health emergency drug that will be sterile, an indication to that effect, and

(ii) a certificate from an inspector indicating that the buildings, equipment, practices and procedures of each fabricator, packager/labeller and tester meet the applicable requirements set out in Divisions 2 to 4 or, alternatively, other evidence establishing that those requirements are met; and

(c) the public health emergency drug belongs to a category of drugs that are authorized to be imported under the establishment licence.

37 Sections C.08.009.04 and C.08.009.05 of the Regulations are replaced by the following:

C.08.009.04 Sections A.01.040, C.01.004.1 and C.01A.006 and Divisions 2 to 4 of this Part, other than the following provisions, do not apply in respect of the importation of a public health emergency drug under section C.08.009.03 by the holder of an establishment licence:

(a) sections C.02.003.1, C.02.004 and C.02.006, as they apply to the storage of the public health emergency drug by the holder;

(b) subsection C.02.012(1);

(c) section C.02.012.1, as it applies to the storage of the public health emergency drug by the holder;

(d) sections C.02.013 and C.02.014;

(e) section C.02.015, as it applies to the storage and transportation of the public health emergency drug by the holder;

(f) subsection C.02.021(1), as it applies to the storage of the public health emergency drug by the holder;

(g) subsection C.02.022(1);

(h) section C.02.023;

(i) subsection C.02.024(1); and

(j) section C.03.013.

C.08.009.05 Despite anything in these Regulations, the holder of an establishment licence may distribute a public health emergency drug that they have imported under section C.08.009.03 if

(a) the Chief Public Health Officer provides the Minister with the name of the public health emergency drug and the civic address of the place where it will be stored after distribution; and

(b) the public health emergency drug is distributed to a person who will store it at that place.

38 (1) Subsection C.08.011.2(2) of the Regulations is amended by adding the following after paragraph (c):

(c.1) section C.02.012.1, as it applies to the storage of the new drug by the holder of an establishment licence;

(2) Subsection C.08.011.2(2) of the Regulations is amended by adding "and" after paragraph (i), by striking out "and" after paragraph (j), and by repealing paragraph (k).

39 (1) Subsection C.10.001(5) of the Regulations is amended by adding the following after paragraph (c):

(c.1) section C.02.012.1 as it applies to the storage of the drug by the licensee;

(2) Subsection C.10.001(5) of the Regulations is amended by adding "and" after paragraph (i), by striking out "and" after paragraph (j), and by repealing paragraph (k).

40 Subsection C.10.002(2) of the Regulations is amended by adding the following after paragraph (c):

(c.1) section C.02.012.1 as it applies to the storage of the drug by the licensee;

Medical Devices Regulations