1100-8215 112 Street NW Edmonton, AB T6G 2C8 Tel: 780-990-0321 Tel: 1-877-227-3838 Fax: 780-990-0328 Web: abpharmacy.ca

Healthy Albertans through excellence in pharmacy practice

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Abid Mavani
Fatality Inquiry Coordinator
Alberta Justice
Civil Litigation Team
9th Floor Peach Hills Trust Tower
10011-109 street
Edmonton, Alberta T5J 3S8
email: abid.mavani@gov.ab.ca

sent by email

Dear Mr. Mavani,

Re: Alexandru Gabriel Radita – Public Fatality Inquiry – Response to Recommendations

The Alberta College of Pharmacy (ACP) has reviewed the report of Justice S.L. Van de Veen resulting from her inquiry into the death of Alexandru Gabriel Radita I am responding to her Honor's recommendations, outlined in your letter dated March 4, 2024 that may impact ACP.

Recommendation 1 -It is recommended that the College of Pharmacy address the evidence at the Inquiry concerning the role the pharmaceutical industry played in the tragic case of Alexandru Radita. The Inquiry is concerned the same practices by pharmacies may exist today and that there may be a need for the college to oversee regulatory safeguards relating to the provision of insulin without prescription by busy pharmacists at the request of caregivers of child patients.

ACP Response – ACCEPTS in PRINCIPLE - Over the past two years, ACP has been reviewing and updating its Standards of Practice for Pharmacists and Pharmacy Technicians (SPPPT), and the Standards for the Operation of Licenced Pharmacies (SOLP). The following commentary cites how the newly approved standards address this recommendation.

Insulin is a schedule 2 drug in Alberta. Section32(b) of the *Pharmacy and Drug Act* requires that schedule 2 drugs may only be sold in the dispensary of a licensed pharmacy under the direct supervision of a pharmacist.

SPPPT Standard 7.1.1 requires a comprehensive assessment process each time a pharmacist provides a restricted activity or professional service to a patient, including selling a schedule 2 drug such as insulin.

With respect to pharmacists being busy, the above-mentioned standard is not optional and must be followed in all circumstances when a schedule 2 drug is sold. Standard 2.2.2 of the new standards, requires that a regulated member must not practise under conditions imposed by a proprietor, another regulated member, or any other individual or organization that may compromise their professional independence, judgement, or integrity, or provide insufficient staff levels or inadequate resources to provide safe, effective patient care.

Standard 2.1.1(b) and 2.2.1 of the SOLP require that licensees and proprietors provide regulated members the resources they need to meet their obligations to the standards, including the ones mentioned above. SOLP Standard 2.1.2(a), specifically prevents proprietors from imposing any condition that compromises the regulated member's professional independence, judgement, integrity, or ability to comply with the legislative framework.

Recommendation 2 -It is recommended that pharmacists be required to not only maintain records of providing drugs including insulin, without a prescription from a physician, but also be required to upload their records on to NetCare so that these transactions can be accessed by other NetCare providers, including other pharmacists. There is doubt that there was an ongoing record on NetCare concerning the irregular pattern and amounts of insulin provided by pharmacists in the Radita case over an extended period of time.

ACP Response – ACCEPTS - Selling schedule 2 drugs including insulin is a restricted activity under s1.3(1)(h) of the *Health Professions Act* (HPA).

Domain 7 of the new SPPPT provides direction that schedule 2 purchases, such as the insulin, must be documented.

SPPPT Standard 7.1.1 (e) requires a pharmacist to document the details of care to enable collaboration and continuity of care each time the pharmacist provides a restricted activity or professional service to a patient.

SPPPT Standards 7.10.1, 7.10.2, and Appendix E, provide detailed direction of how and what information must be documented.

SPPPT standards 8.8.1(b) and (c) require that a regulated member record in the patient record, the sales of each schedule 2 drug sold, and that these records are uploaded to NetCare as soon as reasonably possible. Supporting this, SOLP standard 5.3.1 requires that regulated members have access to NetCare and that information is submitted and received using real time integration that transmits this information at the time the schedule 2 drug is sold (implementation of the requirement for real time integration will be delayed to July 1, 2026 to ensure system readiness.)

Recommendation 3-The existing Alberta College of Pharmacists Code of Ethics, principal 1(7) states that pharmacists and pharmacy technicians use their knowledge, skills and resources to "safeguard the well-being of each patient and in particular any patient who is vulnerable." It is recommended that the College consider standards specifically requiring pharmacists to carry out an assessment of patients who rely upon them in a long-term situation for drugs that can be provided by pharmacists without a prescription, such as insulin, especially if a caregiver repeatedly fills the prescription for a child who has never been seen by the pharmacist.

ACP Response – ACCEPTS - As noted in the analysis of Recommendation 1, standard 7.1.1 of the new SPPPT requires a comprehensive assessment process each time a pharmacist provides a restricted activity or professional service to a patient, including selling a schedule 2 product such as insulin.

Additionally, SPPPT standards, 7.2, 7.3, 7.4, 7.5, 7.8, 7.9, and 7.10, and all the respective subsections therein provide the specific requirements for this comprehensive assessment that includes:

- Assessing why patients are seeking care.
- Collecting appropriate information for care.
- Evaluating information collected and identifying care options.
- Making evidence-informed decisions.
- Supporting patients in making care decisions and implementing care.
- Monitoring and follow up.
- Documenting in the patient record.

Recommendation 4 -It is further recommended that if a caregiver fails to produce the patient for the assessment requested by a pharmacist that the pharmacist consider reporting the matter to Social Services in accordance with the provisions of section 4 (1) of the Child, Youth and Family Enhancement Act. This section requires any person who has reasonable and probable grounds to believe that a child is in need of intervention shall forthwith report the matter to a director or a police officer.

ACP Response – ACCEPT - While it is common for a pharmacist to provide care to a patient through the use of a patient agent, the appropriateness of this relationship is not to be automatically assumed, and the pharmacist has responsibilities in this regard. SPPPT standard 1.1.3 requires that the regulated member must determine whether providing care through a patient agent is in the best interests of the patient. This includes assessing:

- the expressed wishes of the patient,
- whether the patient's health creates a barrier to communication,
- whether the patient is capable of providing informed consent for the regulated member to communicate with the patient's agent, and
- whether the patient is located in the area where the service is being provided or can be contacted by telephone or other technology that allows for communication with the patient.

Further to that, SPPPT standard 7.3 requires pharmacists to collect all appropriate information pertaining to each patient's healthcare history and current signs, symptoms, and stated health concerns. Standard 7.3.3 then permits a pharmacist to conduct a physical examination when required. This examination must be in-person with patient present, as standard 3(a)(ii) of the Standards of Practice for Virtual Care prohibits an assessment from being conducted virtually

when the patient requires a physical assessment or an assessment that requires in-person patient observation.

This would prevent a pharmacist from simply selling a schedule 2 drug like insulin without performing an assessment.

Finally, SPPPT standard 1.1.4 has been approved, requiring that if, during the assessment described in Standard 1.1.3, a regulated member determines that the wellbeing or safety of a patient, and in particular, a vulnerable patient, is at risk, the regulated member must immediately report the matter to the police or another appropriate authority.

Recommendation 5 -It is recommended that the College of Pharmacy collaborate with Alberta Child and Family Services and other stakeholders in the examination of the general alert system described in recommendation number 5 of the Recommendations Relating to Child and Family Services found at page 36 and 37 of this report.

ACP Response – ACCEPT in Principle - ACP welcomes collaboration to contribute to safer communities. Should Alberta Child and Family Services initiate a project to examine the feasibility of a general alert system, ACP is happy to participate as determined appropriate.

Sincerely,

Greg Eberhart, BSc. Pharm

Registrar