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25 Furbacher Lane
Aurora, ON L4G 6W3
Toll Free: P 1-866-RX4-PETS
1-866-794-7387
F 1-866-FAX-RXRX
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www.svprx.ca

June 30, 2016

Re: OCP Seeking Feedback on Proposed Implementation Timeline for NAPRA's Sterile Compounding Standards

Summit Veterinary Pharmacy Inc. welcomes the opportunity to comment on the OCP (Ontario College of Pharmacists) consultation regarding the implementation of the National Association of Pharmacy Regulatory Authorities' (NAPRA) two "Standards" documents regarding compounding of sterile preparations:

[Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations](#)

[Standards for Pharmacy Compounding of Hazardous Sterile Preparations](#)

Both documents went through no less than four (4) drafts before reaching what are now "final" versions. NAPRA is optimistic that pharmacy provincial regulatory authorities (PRAs) will adopt these as Standards of Practice within the various provinces/territories. However, they have not been circulated to all practising pharmacists for comment; only now are some PRAs seeking input from members, and in some cases (e.g., Ontario), only in terms of implementation timeline, not as to content of the documents.

Pharmacy compounding is already held to a high standard for patient safety reasons, as well as for consistency of preparations, through pharmacists adhering to the requirements set out in the *United States Pharmacopeia* (USP 39-NF 34). In particular, chapters <795> (non-sterile compounding) and <797> (sterile compounding) address compounding. A recent USP call for comments on proposed amendments to USP<797> resulted in a revamping of that chapter, which will be published on November 1, 2016 and go into force on May 1, 2017 (assuming no further amendments are made).

Similarly, a newly-proposed chapter to the USP has received substantial scrutiny (USP<800>, *Hazardous Drugs -- Handling in Healthcare Settings*). This chapter will be relevant to all healthcare personnel who "handle HD preparations and all entities that store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices)" [*Sec 1. Introduction and Scope*, USP<800> Feb 1, 2016]. The opening sentence of the chapter states: "*This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection.*" So, it includes patient safety rather than exclusively worker safety, as well as including professions other than pharmacy.

Contemporaneous with these USP consultations, NAPRA created its own documents, both in the vicinity of 100 pages in length. By comparison, the current version of USP<800> is around 20 pages in length, and the most recently circulated version of USP<797> (for which comments closed January 31, 2016) is 58 pages. The NAPRA documents, if adopted as "practice standards" by regulatory colleges, would result in members of those colleges being expected to adhere to the Standards or risk being deemed to have committed professional misconduct for "failing to maintain a standard of practice of the profession."

The NAPRA documents create conflict if a compounder adheres to requirements for compounding set out in the internationally-accepted pharmacopeia (USP). They are already "outdated" as their content refers to earlier versions of the USP chapters that have been (or will be) changed prior to the NAPRA documents being accepted and put into

practice. The “hazardous” NAPRA document repeatedly refers to USP<800> (which continues to undergo critical assessment from all facets of healthcare professionals to be affected by its induction into the USP). This creates a dilemma for pharmacists and, in fact, *any* compounding healthcare professional adhering to the USP chapters. They will have to choose which set of standards to follow when conflicts arise between requirements of the two references on a particular topic. If they claim they comply with USP standards, they cannot make such a claim if they compromise that compliance to follow what is mandated by a provincial/territorial licensing body of pharmacy’s own documents (you are either fully USP-compliant, or not).

When the USP proposes revisions to a chapter in its pharmacopeia, it is first posted for stakeholder/public feedback. Such has not been the case for the NAPRA documents. Rather, a very select stakeholder group was consulted, representing only a minority of the total profession.

The OCP has invited public consultation regarding these documents with a deadline of June 30, 2016 [Ref: <http://www.ocpinfo.com/about/consultations/>]. However, the consultation does not invite comments regarding content of the documents; only concerning the proposed timeline to implementation (2 years). It is professionally inappropriate to only comment on the timeline when there may be concerns that the **content** will conflict with internationally-accepted standards for sterile compounding (i.e., USP<797> and associated chapters).

A major area of concern to many professionals should be the virtual elimination of "office-use" procurement of medications by practitioners as permitted by their licensing authorities, due to terminology that suddenly entered into the NAPRA documents during the formative phases of the documents.

To wit, section 3 (“Regulatory Framework”), had stated in **version 2A**:

*"The preparation of medications...must always be carried out within an individual physician-patient-pharmacist relationship (i.e., **from a prescription**) or within a pharmacist-patient relationship for a specific need (e.g., with over-the-counter preparations)..."*

In situations involving requests to compound preparations outside an individual physician-patient-pharmacist relationship, without a prescription, the compounding activities fall under the federal legislative framework" (underscore/bold added).

Various PRAs (medicine, dentistry, veterinary medicine) permit their members to procure “office-use” medications in order to provide the best care to their patients. This is a practice that is recognized, accepted, and condoned provincially & territorially, as well as by Health Canada on a federal basis. Since a legitimate prescription could be written by a qualified healthcare practitioner as “for office-use,” it would be recorded as being sold to “patient Dr. X” and also as prescribed by “Dr. X” under the basic parameters of a prescription (that a drug identified in the prescription be dispensed to the person named in the prescription...being the prescriber in the case of “office-use”). *Food & Drug Regulations* section C.01.043(1)(b) allows the sale by a person (entitled to possess such drugs) of a prescription drug to a practitioner. No reference to “by a prescription” is made; in fact, the section used to read “A person may sell a Schedule F drug, without having received a prescription therefor, to...” That permits a practitioner to simply buy such drugs from a pharmacist; but the use of a prescription for such orders ensures a record of sale in pharmacy practice from source to recipient (including upon a written order of prescriber for a narcotic, which would then require that its sale be reported in the narcotic sales report using the name of the prescriber as both patient and prescriber).

The **final versions** of both documents now read as follows:

"The preparation of medications (pharmacy compounding)...must always be carried out within a prescriber-patient-pharmacist relationship." [DELETED: "(i.e., in the form of a patient-specific prescription)" and "or within a pharmacist-patient relationship for a specific need (e.g., with over-the-counter preparations)"]

"In situations involving requests to compound preparations outside of a prescriber-patient-pharmacist relationship, in the absence of a patient-specific prescription, the preparation activities fall under the federal legislative framework" (underscore/bold added).

Concern was voiced to both OCP and NAPRA prior to version 3 being released, that the use of "healthcare professional-patient-pharmacist" terminology should be used instead of "prescriber-patient-pharmacist" (to be consistent with what is found in Health Canada's POL-0051 document "*Policy on Manufacturing and Compounding Drug Products in Canada*"). We also urged the removal of "**patient-specific**" which arrived in version 3. (Version 3 also recognized contributions from an American USP consultant not previously listed). Significantly, "office-use" is not considered legitimate by the USFDA, which has been trying to eliminate this aspect of pharmacy practice for years, in part through use of the term "patient-specific prescription."

"Office-use" procurement is acceptable, essential practice within various professions across Canada and is permitted by standards established by individual regulatory authorities of medicine, dentistry, and veterinary medicine in order to properly serve patients' needs. The OCP itself published an article in its Winter, 2016, edition of "Pharmacy Connection" about the Ontario *Narcotic Safety and Awareness Act*, identifying to pharmacists how monitored drugs for "office-use" should be captured in the reporting system. The OCP states on its website page for this consultation: "Yes (office use preparation will be permitted)" -- but conditionally, "within the context of these standards." It is therefore necessary to define that condition within the standards (it does not appear) -- especially when many other Canadian PRAs recognize the practice of "office-use" through policies and documents relevant to those professions.

There will be significant impact upon practices should these documents be accepted without a clear statement included **within the documents** that permits "office-use" by including it visavis the term "patient-specific." Considerations include:

- 1) Adverse impacts upon readily-available medications for patient (human) and hospital needs, including emergencies, TPN therapy.
- 2) Adverse impacts upon emergency room aspects of veterinary clinic requirements (on-hand medications for emergencies such as poisonings, infections, trauma) due to necessary lead times to ensure sterility/endotoxin testing.
- 3) Nothing should preclude "office-use" preparations when such practice is permitted within various professions (dentistry, veterinary medicine, human) as it is considered essential in terms of good patient care (best practices) that practitioners have adequate stock on hand to dispense in emergency situations, as well as on weekends.
- 4) The proposed Standards are already outdated, due to recent/pending changes to the official chapters in the USP (to which these documents make reference). Examples: these documents refer to three classes of compounded sterile preparations when there are to be only two in the revised USP<797>. The revised USP<797> also introduces the aspect of "in-use time" which is not part of the NAPRA documents, but will need to be a consideration when creating compounded sterile preparations.

The OCP consultation page states that one would be expected to adhere to the NAPRA documents if one wanted to continue with sterile compounding, with no allowance for one's already being compliant with USP standards.
- 5) Health Canada recognizes "office-use" dispensing; they advise pharmacists on how to report the sale of "straight narcotics/controlled substances" when made in such fashion (i.e., show patient name as being the prescriber, so that the "patient" and "prescriber" fields will bear the same name). This allows auditing/traceability of such substances after they leave the pharmacy, keeping the practitioner receiving the drugs accountable for what is done with them afterwards.
- 6) In Ontario, the *Narcotic Safety and Awareness Act* has a code for reporting "office-use" sale of monitored drugs through the NMS.
- 7) There is huge outcry in the USA over the USFDA interpreting the "Drug Quality and Security Act" (DQSA) as not permitting "office-use" dispensing. While the USFDA refuses to recognize *any* compounding as legitimate, Congress (most recently as June 20, 2016) wrote to the Commissioner of the USFDA and reminded

him that on April 19, 2016, the USFDA was directed to “allow for office-use compounding.” That letter stated further:

“Prior to the passage of the Drug Quality and Security Act (DQSA) of 2013, FDA circulated a draft Compliance Policy Guide (CPG) in 2012 to Congress that recognized office-use as legitimate and permissible...The DQSA did not change the statutory language in 503A that was the basis of that CPG. During the consideration of the DQSA, six Members of Congress, on a bipartisan, bicameral basis, made statements in the Congressional record to clarify that the intent of the legislation was to preserve patient access to medications compounded for office-use...Unfortunately, the FDA has to date ignored that congressional intent and substituted the agency's own, incorrect interpretation of the law in implementing and enforcing the DQSA.”

The letter was signed by 61 members of Congress, at least one of whom is a pharmacist.

Significantly, the very terms “patient-specific” and “office-use” are not defined in the NAPRA documents. These critical terms are incorporated into both documents, which pharmacy PRAs are now considering adopting without further modifications. The terms *must* be defined in the documents in which they are used, as is done with other important terms found within the documents. One such definition suggested is:

“patient-specific” shall include “office-use” prescription orders of a practitioner entitled to prescribe in a province/territory of Canada.

Summit Veterinary Pharmacy Inc. already complies with the current version of USP<797>, which is the internationally-recognized standard for sterile compounding. Summit Veterinary Pharmacy Inc. has also created extensive Standard Operating Procedures (SOPs) as is required of anyone performing sterile compounding. Therefore, a 2-year timeline to implementation of the non-hazardous sterile compounding document should be adequate, provided it is consistent with the requirements of the USP. Should it be found, however, that the NAPRA standards conflict with USP standards in any areas, the need to evaluate and resolve any conflicts would arise, possibly affecting what was a reasonable 2-year timeframe to implementation.

As a final comment, there should not be varying timelines of implementation based on type of practice, or costs, etc. The focus of these “standards” are to be on patient safety. If risk is truly the driving concern, then sterile preparations are a concern now, wherever sterile compounding is undertaken. Giving 2 to 5 years to comply means that unless it is a new startup pharmacy, a pharmacy performing sterile compounding is placing the patient at risk if not in compliance (or if allowed to perform these actions short of full compliance to standards).

Any pharmacy performing sterile compounding should already have SOPs in place, as is required by the licensing body (Ontario), along with an internal quality assurance program. It would be unfair to allow some existing pharmacies to have 2 years, and others up to 5 years to comply based on cost concerns (a factor impacting upon all practice environments requiring modification of premises and budgetary considerations).

The bar must be set equally for all sterile compounders. While it may be difficult to say “no sterile compounding until you comply” there is no other alternative if “protection of the public interest” is truly the mandate of a regulatory body. It takes but one contaminated preparation disaster to instantly make front page news and impact adversely upon the entire profession; but it can take years to reverse that image in the eyes of the public, even if only one pharmacy commits the faux pas.

Respectfully,

Stephen Organ
President

Don Organ, R.Ph.
Chair

Ed Bielawski, R.Ph.
Designated Manager

Kim Ruthig, R.Ph.
Chief, Regulatory Compliance