

May 11, 2015

Ontario College of Pharmacists
Re: Open Consultation Feedback
483 Huron Street
Toronto ON M5R 2R4

Dear Mr. Moleschi:

RE: Proposed Changes to the Drug and Pharmacies Regulation Act (DPRA)

The Ontario Pharmacists Association (OPA or the “Association”) welcomes the opportunity from the Ontario College of Pharmacists (OCP or the “College”) to comment on the proposed changes to the Drug and Pharmacies Regulation Act (DPRA), 1990, O. Reg. 58/11.

The Ontario Pharmacists Association is committed to evolving the pharmacy profession, and advocating for excellence in practice and patient care. As Canada’s largest advocacy organization, and continuing education and drug information provider for pharmacists, the Association represents pharmacy professionals across Ontario. By leveraging the unique expertise of pharmacy professionals, enabling them to practice to their fullest potential, and making them more accessible to patients, OPA is working to improve the efficiency and effectiveness of the healthcare system.

It is generally accepted that the profession of pharmacy has undergone significant changes since the DPRA was originally enacted in 1990, and that change will continue as the needs and expectations of Ontarians shift and the health system grows and evolves. The passage of *Bill 21: Safeguarding Health Care Integrity Act* in December 2014 acknowledged the need for legislative and regulatory change by extending the College’s authority to license and inspect pharmacies within public and private hospitals, while ensuring sufficient flexibility for OCP to exercise future authority over institutional pharmacy locations. To enable this authority now and to introduce flexibility for practice and professional evolution moving forward, as well as removing unnecessary duplication, it is recognized that broad changes to the DPRA would be required. Under its current language, the DPRA and its regulations are overly rigid and cumbersome to enable practice change quickly. To this end, OPA strongly supports the concept of regulatory overhaul to introduce great flexibility and responsiveness for practice and professional evolution. However, OPA urges caution and careful consideration with regard to the intent and enforceability of certain regulated activities and operational requirements as they get rewritten or moved into policy, guidelines or standards of practice; this will help to ensure that neither gets lost or diluted in transition, thereby contributing unintentionally to risks to patient care and safety, whether directly or indirectly.

OPA acknowledges that it is the objective of this consultation to effect changes that will modernize the DPRA. With this in mind, some language of the regulations will be:

- Reworded for increased clarity, flexibility, and responsiveness;
- Moved into policy, guidelines and standards of practice; and
- Eliminated altogether, especially if that language is duplicated in other pieces of legislation or regulation.

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With this process, the goal of this initial consultation is to protect the intent of O. Reg. 58/11 of the DPRA. It is also understood by OPA that any new policies, guidelines, and standards that have language that deviates from the intent expressed in the original regulations will require a formal consultation process. Accordingly, the Association pledges its support by adopting a leadership role for pharmacy stakeholders in the development of these policies, guidelines, and standards in collaboration with OCP.

Throughout the overall process, this consultation had been particularly challenging as the Association had no way of knowing which elements would be protected and which would be deemed obsolete and unnecessary. Notwithstanding, OPA will be offering commentaries through this submission to articulate the perspectives of the Association on behalf of all its members. Because of the underlying uncertainty as to the final language of the new regulations, policies, guidelines and standards, OPA offers cautious support to the proposed amendments except for those areas where noted otherwise. Our support for the changes expressed in this submission should be qualified on the premise that the corresponding changes will be added into OCP policies, guidelines and standards, and that such policies would be circulated for broad stakeholders' input prior to being approved by OCP Council.

Due to the extent of the proposed amendments to the DPRA regulations, this submission will not include any commentary for sections on which OPA has no issues, concerns or modifications.

PART II – DRUG SCHEDULES

- *Sale of Schedule III Drugs [Newly proposed Section 4(c)(i)]:*

Schedule III drugs shall only be available for sale from, (i) the dispensary or an area in the pharmacy that allows for self-selection of drugs by patients and where a member is available for consultation.

The language proposed states that a “member” would need to be available for consultation. Insofar as OCP classifies pharmacy technicians as “members”, this language could imply that a pharmacy technician could provide the consultation if asked by a patient.

Under this language, OPA cannot support section 4(c)(i) and calls for an amendment specifying that a “pharmacist or pharmacy student/intern working under direct supervision of a pharmacist shall be available for consultation and shall supervise the sale of Schedule III drug products”.

OPA has been made aware of the fact that there are non-pharmacy vendors that have been engaged in the procurement and resale of Schedule III, and in some instances Schedule II, drug products. Currently, if a complaint or notification is made to the College regarding such practices, a cease and desist letter gets issued to the non-pharmacy vendor. Under the existing process, no further follow-up is typically instituted, and in general, seeking injunctions is limited to matters that are deemed to

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have broad impact on population spectrum and patient care. While not necessarily a part of the amended DPRA regulations, but as a means to ensure protection of the public is upheld, the current process and/or mechanism needs to be articulated and fortified so that it mitigates occurrences of having Schedule II and/or III drug products being sold in non-accredited locations.

As this is a national issue, OPA will confer with the College, the Canadian Pharmacists Association (CPhA) and the National Association of Pharmacy Regulatory Authorities (NAPRA) to identify and implement such a process or mechanism.

PART III – CERTIFICATES OF ACCREDITATION: ISSUANCE AND RENEWAL

- *Qualifications for the Issuance of a Certificate of Accreditation [Newly proposed Section 8]:*

OPA provides qualified support for the proposed changes to Part III, Section 8 of the DPRA. This support hinges on the condition that the intent and enforceability of current regulatory language [original regulation sections 8.(1)(3)i to 8.(1)(3)ix] will be suitably captured in the policies and guidelines yet to be developed by the College, and that the OPA is engaged through the drafting and consultation process.

- *Qualifications for Renewal of any Class [Newly proposed Section 14]:*

OPA provides qualified support for the proposed changes to Part III, Section 14 of the DPRA. This support hinges on the condition that the intent and enforceability of the current regulatory language [original regulation section 16] will be suitably captured in the policies and guidelines yet to be developed by the College, and that the OPA is engaged through the drafting and consultation process.

PART IV – STANDARDS FOR ACCREDITATION AND OPERATION

- *Requirements of a Pharmacy [Newly proposed Section 19]:*

While OPA understands and supports the practicality of shifting to a more flexible model of accreditation standards and requirements for pharmacy operations, the Association is nonetheless cautious about how these standards and requirements will be addressed in the yet to be drafted policy and process documents. Furthermore, there is something to be said for the value of the prescriptive language expressed in the current regulations through sections 21 through 37. The original checklist-type language, while outdated and relatively inflexible, conferred to pharmacy owners some measure of defined expectations and a level playing field for all pharmacies. With the proposed changes, the new section 19 transfers many decisions to the discretion and interpretation of the pharmacy owner. OPA recognizes the unique needs of various pharmacy practice settings, and realizes the levels of variation in applying individual interpretation and discretion.

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As a general recommendation for this Part, **OPA suggests that some degree of minimum expectations be established for any practice setting that would be expressed through guidelines and that would be deemed appropriate by any reasonable person engaged in the practice of pharmacy for a guaranteed minimum level of service delivery to patients.**

The following are specific sections for which OPA has a comment or concern:

- Section 19(b)

Every pharmacy must be suitable for the pharmacy services provided therein;

This section speaks of “suitability” for practice as determined by the pharmacy owner. What an individual pharmacy owner defines as suitable might differ from what the College, another operator, another pharmacist employed by that owner, or in some instances what a patient might define.

OPA believes that **there is a need for guidelines to be provided to ensure a minimum level playing field is realized.** This will ensure that a minimum threshold exists to provide support to all pharmacy owners and to ensure patient safety.

- Section 19(i)

Every pharmacy must have available the references and resources that are required by members practising in the pharmacy to meet the standards of practice of the profession and to support the pharmacy services they provide;

This section relates to the “availability of references and resources” to support pharmacy practice. The newly proposed language no longer directs the owner to maintain a specific set of references and resources to support his/her pharmacists in the provision of care. Recognizing the high costs that are often associated with the maintenance of a library of references, it is feared by the Association that decisions to maintain or discontinue those references and resources will be made based more on cost-savings and not on current or future clinical need. In addition, and notwithstanding the increased availability and access to online resources, pharmacists are continually challenged with operational constraints and may not have either the time to adequately research a particular clinical question or the ability to understand conflicting messages between references. Furthermore, it is important to also note that some pharmacies don’t allow internet access.

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OPA does not support these proposed changes to the regulations and urges the maintenance of the existing language of O. Reg. 58/11 as it pertains to the availability of pharmacy references. An approved, unbiased and credible drug information service enables frontline pharmacists to have ready access to fully researched responses or insights into clinical questions and dilemmas while providing uninterrupted service to patients within the pharmacy. Continuation of a mandated drug information subscription service also enables and facilitates intra-professional dialogue on these clinical questions to determine the best possible solution or recommendation for relevant healthcare providers and with the patient's best interest in mind. A more substantive and thorough discussion on this particular matter can be found in **Appendix 1** to this submission.

- *Existing clauses, Sections 29 – 32, 36, and 37 refer to the “safety and security in remote dispensing locations”*

Whereas OPA understands and supports the removal of these sections from the DPRA regulations for eventual inclusion in the standards of practice, we nonetheless qualify this support pending our review of the language within the yet to be drafted standards. It is critical that the eventual standards maintain the same intent and degree of enforceability for pharmacies operating a remote dispensing location.

In general, there is a need to address the numerous questions and areas of concern identified in Part IV of the DPRA regulation to ensure patient safety is protected and upheld. Therefore, **OPA recommends that either more prescriptive language should be retained in the DPRA regulation to entrench a minimum set of standards and expectations for owners, or that more prescriptive language be added into the standards of pharmacy practice or in guidelines, policy and process documents to be produced by the College.**

PART V – ADVERTISING

- *Requirements for Schedule I Drug Advertising [Newly proposed Sections 29(b)]:*

In consideration of the suggested changes to the DPRA regulations on advertising requirements, OPA has had much discussion on the matter and it is quite clear that there are many potential impacts and consequences, some of which may be unintended, that should be carefully considered by the College, the Association and members in general. Some of these impacts and consequences might be internal to the profession and address competitive issues, while others might be broader and more societal in nature that could lead to unforeseen challenges downstream.

For this DPRA consultation, it is OPA's understanding that in conjunction with the draft regulations, the College will be applying a new consultation framework in the drafting of new standards, policies

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and guidelines to ensure stakeholders are provided the opportunity to review proposals and provide input. It is also OPA's understanding that this input is required to ensure that the intent of the proposed changes reflect practice and that, together with the regulations, are enforceable. OPA is supportive of this approach as it permits a more substantive and focused discussion on matters that may have significant impacts in both the short and longer term for the profession, the business and patients in general.

OPA feels that the issue of advertising, as currently written in the DPRA O. Reg. 58/11, should be amended to exclude price advertising as it relates to Schedule I drug products. The Association is highly concerned with the societal message that drug price advertising of Schedule I drug products sets. In a profession that has been working hard to shift the focus away from the product and more appropriately to the patient, facilitating drug price advertising might inadvertently lead to increased commoditization of prescription medication and convert "patients" into "price-savvy consumers" looking for the best deal on the drug of the day. It is entirely foreseeable that price shopping would ensue, thereby fragmenting their medication profile which is clearly not in the patient's best interest.

To this end, and for the purposes of this submission, OPA will restrict its comments to the proposed regulatory change solely as it relates to language on Schedule I drug price advertising. This does not preclude our perspective on many other elements of advertising, including but not limited to Schedule II drug products and professional services.

Therefore, at this time, with a view that the proposed amendment is seeking to change the language within the regulation to remove the restriction brought on by the "15/10" rule, **OPA does not support this change and is proposing a more rigid approach that effectively would prohibit advertising of Schedule I drug price advertising completely.**

On other matters related to advertising, presumably pursuant to new policy, standards and/or guideline development, we look forward to engaging with the College and other pharmacy stakeholders.

- Definitions and Advertising Requirements [Newly proposed Sections 29(a)(g)]:

In addition to the comments and recommendations expressed regarding Schedule I drug price advertising, OPA also calls for greater clarity in newly proposed section 29(a)(g) that deals with advertising requirements surrounding the use of a term, title or designation:

29.a No person shall advertise or permit, directly or indirectly, another person to advertise a pharmacy or its services in a manner that,

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(g) Inappropriately uses a term, title or designation to indicate or imply that a member practising in the pharmacy has a specialization in the profession;

Specifically, OPA seeks clarity on the word “inappropriately”. **It is OPA’s position that it may be in the patient’s best interest for them to seek out the services of a pharmacist with a specific set of professional credentials, title, or designation so long as there is no declaration of superiority or any other comparator of one pharmacist over another.** While this is being proposed by OPA for the community pharmacy sector, the Association also recognizes that the **use of professional credentials, terms, titles, and designations for pharmacists working in hospitals is not only commonplace but is actually helpful to other healthcare providers** to identify and seek out pharmacists with a specialized training.

PART VI – PROPRIETARY MISCONDUCT

- Acts of Proprietary Misconduct [Newly proposed section 32]:

32. *The following are acts of proprietary misconduct for the purpose of section 140 of the Act:*
18. *Entering into any agreement that restricts a person’s choice of a pharmacy or pharmacist without the consent of that person.*

OPA supports the notion that it is proprietary misconduct if a pharmacy owner enters into any agreement that restricts a person’s choice of a pharmacy or pharmacist without the consent of that person. It is OPA’s position that agreements that impact prescription coverage and reimbursement can also significantly impact, and in some instances, completely prohibit patient choice. Therefore, **the Association recommends adding language to this clause that includes entering into agreements that limit and/or deny a patient’s medication coverage, without consent, so that it would also be considered as an act of proprietary misconduct.**

Further to this, while the development of newly proposed Section 32.18 saw the removal of the word “written” as it applies to consent, **OPA strongly recommends the addition of the concept of “expressed consent” of the patient/agent as a means of formally capturing the patient’s permission.**

- Acts of Proprietary Misconduct [Newly proposed section 34]:

32. *The following are acts of proprietary misconduct for the purpose of section 140 of the Act:*
(24) *Inappropriately using a term, title or designation in respect of the practice of a member practising in the pharmacy.*

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To supplement OPA's commentary on section 29(a) (g) in Part V – Advertising regarding the use of terms, titles and designations, **OPA would like to obtain more clarity on the use of the term “Inappropriately”.** Furthermore, as practice continues to evolve and as regulations and policy become more flexible, so too should regulatory language regarding the use of a pharmacists' designation. OPA would never imply that the “appropriate” use of one's term, title and designation constitutes proprietary misconduct, and seeks to know the definition of the word “inappropriate”.

- Acts of Proprietary Misconduct [Newly proposed section 34]:

34. It is a conflict of interest for a responsible person to do, or to cause or permit another person to do, directly or indirectly, any of the following:

(e) Enters into any agreement or arrangement that adversely influences or appears to adversely influence the exercise of professional expertise or judgment or the ability of a member working in the pharmacy to engage in the practice of the profession in an ethical manner or in accordance with the standards of practice of the profession.

OPA fully supports the addition of the newly proposed section 34(e).

FINAL COMMENTARY AND SUMMARY OF THE OPA SUBMISSION

OPA appreciates the opportunity to comment on the proposed amendments to the Drug and Pharmacies Regulation Act regulations. OCP is to be commended for its outreach to stakeholders early on in the consultation period and for their preparation of comprehensive consultation documents to assist with the mapping of current to new language, and where deemed appropriate, in providing written rationale. It is acknowledged that the proposed revisions are very broad, and go far beyond adding or changing single provisions. OPA accepts that in order to introduce greater flexibility for practice and professional evolution moving forward, it is valuable to make such broad changes. It is also important to remove unnecessary duplication in messaging.

Based on recent conversations with OCP, OPA is encouraged that the preliminary goal is now to reframe much of the language contained in DPRA O. Reg. 58/11 into either a simpler, non-duplicative manner or into new policies, guidelines, and standards of practice, all the while protecting the intent and enforceability of the current regulations. OPA understands that any development of new policy, guidelines and standards that introduce a shift from the original intent expressed in O. Reg.58/11 will be subject to a new stakeholder consultation process. We are pleased to commit Association time and resources to this process and to take a leadership role for pharmacy stakeholders.

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Notwithstanding the articulated shift in process, OPA has proceeded with the provision of commentary, and where necessary, recommendations based on the proposed changes introduced on March 10, 2015. Our comments and recommendations, therefore, are qualified and contingent on the wording, intent and enforceability of new regulations, policies, guidelines and standards, many of which have yet to be developed. OPA's primary focus has been to ensure that critical requirements currently articulated in the DPRA O. Reg. 58/11 do not get lost or diluted in their transition into new regulation, policy, standards of practice and guidelines. In the absence of such cautions, there is the potential for some unintended and undesired risks to patient care and safety, whether directly or indirectly.

The Association would like to reiterate its support toward the development of the needed policies and process documents, and where possible take the lead on drafting proposed guidelines to help provide guidance to pharmacy operators.

Should you have any questions or comments regarding the OPA submission, please do not hesitate to contact me at 416-441-0788.

Yours truly,



Dennis A. Darby, ICD.D
Chief Executive Officer

cc: Deb Saltmarche, Chair of the Board, Ontario Pharmacists Association
Sean Simpson, Vice Chair, Ontario Pharmacists Association
Allan H. Malek, Senior Vice President, Professional Affairs, Ontario Pharmacists Association
Sherif Guorgui, Vice President, Pharmacy, Ontario Pharmacists Association
Connie Campbell, Director, Finance & Administration, Ontario College of Pharmacists
Anne Resnick, Deputy Registrar, Ontario College of Pharmacists



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APPENDIX 1

Supplemental Information and Commentary Regarding Part IV – Standards for Accreditation and Operation

Requirements of a Pharmacy [Newly proposed Section 19(i)]



August 5, 2014

Mr. David Hoff
Chair, Accreditation Committee
Ontario College of Pharmacists
483 Huron Street
Toronto, ON
M5R 2R4

VIA EMAIL: council@ocpinfo.com

Dear Mr. Hoff:

The Ontario Pharmacists Association (OPA) welcomes the opportunity to comment on deliberations of the Accreditation Committee of the Ontario College of Pharmacists (OCP) regarding drug information subscription requirements.

The Ontario Pharmacists Association is the largest advocacy organization, and continuing education and drug information provider for pharmacy professionals in Canada, representing more than 14,500 pharmacists, pharmacy students, and pharmacy technicians across Ontario. By leveraging the unique expertise of pharmacy professionals, by enabling them to practice to their fullest potential, and by making them more accessible to all Ontarians, OPA and its more than 8,500 members are working to improve the efficiency and effectiveness of the province's healthcare system.

With reference to the posted minutes of the OCP Council Meeting of March 17, 2014, OPA is aware that the College's Accreditation Committee will be deliberating the requirement within the *Drug and Pharmacies Regulation Act* (DPRA) that makes it mandatory for a pharmacy in Ontario to subscribe to a drug information service approved by Council. As Ontario's leading provider of drug information services to pharmacists working in all areas of practice, including community pharmacies, hospitals and Family Health Teams, OPA and its Drug Information and Resource Centre (DIRC) are well-positioned to comment on this matter, on the benefits of the current regulated model, and on the risks associated with a move toward an optional approach to obtaining drug information. We aim to validate our position by articulating our experience on this matter and speaking to some of the key elements that we believe are essential when assessing drug information services to pharmacists and pharmacies with protection of the public always at the forefront.

EXPERIENCE AND CREDIBILITY:

For more than 15 years, the Ontario Pharmacists Association's Drug Information and Resource Centre has been Canada's leading provider of drug information to healthcare professionals. The Association prides itself on the fact that DIRC services to community and hospital pharmacies and Family Health Teams are delivered by pharmacists with unparalleled access to unbiased pharmaceutical, medical and health-focused databases, as well as clinical resources from Canada, the United States and points across the globe. Under the guidance and support of the director and senior pharmacist, DIRC's 25+ drug information pharmacists bring experience from many different areas of professional practice to the organization, and many carry professional designations and additional training credentials

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(including designations such as CDE, CRE, CAE, CGP, NAMS, as well as post-graduate PharmD)¹. DIRC is highly regarded in provincial and

national healthcare communities as a source for high quality, unbiased drug information. DIRC's corporate clients have included the Workplace Safety and Insurance Board and the Patented Medicine Prices Review Board, and more than 2,600 community and hospital pharmacies. DIRC pharmacists have written for a variety of provincial,

national, and international publications, including *Ontario Pharmacist*, *Pharmacy Connection*, and *Pharmacist's Letter*.

ACCESSIBILITY AND COST:

While OPA acknowledges that technology can greatly facilitate the timely access to drug information resources, it also recognizes that such access might come with significant costs, questionable authenticity, as well as limited functionality and professional context. A subscription to DIRC, and indeed any other approved drug information service, mitigates much if not all of the challenges associated with data source selection.

DIRC takes tremendous pride in its expertise and experience in the selection and navigation of drug information sources and databases. Not only does a DIRC subscription meet the requirements established through the *Drug and Pharmacies Regulation Act R.S.O. 1990, Chapter H.4, O. Reg 58/11* and mirror OCP's Required Reference Guide for Ontario Pharmacies, it goes over and above by including many additional databases and sources to which most individual pharmacies and pharmacists would opt not to subscribe. This additional reach ensures that DIRC pharmacists – and by extrapolation DIRC's pharmacy subscribers – have the most up-to-date and credible sources of information to optimally support patient care and interprofessional communication. DIRC's dedicated contact centre pharmacists routinely undergo training, refreshers, and quality assurance evaluations, and share their approaches to unique or challenging questions internally with their colleagues to ensure that clients are well served with the most up-to-date, evidence-based information. Table 1 identifies some of those online, subscription-only databases and resources to which OPA maintains licences in order to supplement the required resources for pharmacies.

¹ CDE = Certified Diabetes Educator ;
CGP = Certified Geriatric Pharmacist;

CRE = Certified Respiratory Educator;
NAMS = North American Menopause Society

CAE = Certified Asthma Educator;

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TABLE 1: SUPPLEMENTAL DIRC RESOURCES/DATABASE SUBSCRIPTIONS (beyond OCP requirements)

DIRC Databases and Resources (over and above OCP requirements)	Cost Per Database or Resource (annual subscriptions)
John Hopkins Guide	\$25.00
Sanford Guide to Antimicrobial Therapy	\$50.00
Natural Medicine Comprehensive Database	\$3,416.00
Medications & Mothers' Milk	\$80.00
Int'l Journal of Pharmaceutical Compounding	\$5,000.00
IDENT-A-DRUG	\$31.50
King Guide to Parenteral Admixtures	\$395.00
UpToDate™	\$4,555.00
John Hopkins Guide	\$25.00
Sanford Guide to Antimicrobial Therapy	\$50.00
Micromedex	\$36,000.00
TOTAL SUPPLEMENTAL SUBSCRIPTIONS	\$49,627.50

Despite the ease of access the Internet provides for individuals to source health-related information, OPA contends that a mandated drug information subscription service takes all of the guess work out of selecting the most appropriate, credible and practical data sources. Costs associated with an *à la carte* selection of databases can be prohibitive to both pharmacy owners and pharmacists. On the other hand, the multiple licensing costs borne by DIRC are easily amortized across the entire subscriber list and therefore, the costs per client are substantially lower. This allows DIRC to provide its subscribers with access to otherwise very expensive data sources.

EFFICIENCY AND PRODUCTIVITY:

The direct benefit of a mandated drug information subscription service to patient care can also be seen with streamlined navigation of data sources, the time-savings of having another healthcare professional conduct a comprehensive literature search on your behalf, and the invaluable bi-directional, professional dialogue between the pharmacist caller and the drug information specialist to apply the evidence to a specific patient issue. Simply having access to good sources of drug information is no guarantee that an answer to one's question will be simple to find. Key elements in the provision of a response to a drug information query include categorizing the information provided, understanding the context in which it's presented, and translating the available evidence to the specific patient question – and it is this knowledge translation that can often be challenging, time-consuming and frustrating. DIRC's drug information pharmacists are highly skilled at navigating external databases, at accessing internal databases for similar, previously asked questions, and in knowledge translation that allows the pharmacist subscriber to leave with one or more options to help manage a specific patient issue or physician query. Inter- and intra-disciplinary communications facilitate robust decision-making; a mandated drug information service, such as that provided through the DIRC model, would practically ensure such protocols are applied and followed.

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MANAGING COMPLEXITY:

Just as every patient is unique and may range from being uncomplicated to particularly complex vis-à-vis their medication regimen, so too are drug information questions. Managing complexity is closely tied to efficiency and productivity, but deserves to be addressed on its own as it is not simply about time management. Misinformation can have disastrous consequences to patient health outcomes, and so it is essential that all drug-related questions get the time and scrutiny they require. DIRC pharmacists are ideally poised and adept in providing front-line practitioners with timely answers to uncomplicated questions that might otherwise be time-consuming for them to research on their own, thus ensuring that delivery of patient care is not unduly delayed. Furthermore, profound value comes in assisting front-line pharmacists, and the physicians and patients they represent, with the management of highly complex pharmacotherapeutic issues. **Appendix A** provides a small sampling of some of the complex and time-consuming questions submitted to DIRC pharmacists – all of them are actual cases:

As pharmacists in Ontario continue to strive for additional expansion in their scope of practice to include the administration of injections beyond flu shots, to prescribe medications for travel purposes, and to assess and treat common ailments, it will be even more important that they have an unbiased, external resource with whom to consult on these important decisions.

AUTHENTICITY AND CREDIBILITY OF RESOURCES:

With more than 20,000 questions handled by DIRC pharmacists annually, plus those placed through the four other approved drug information services in Ontario, it would be difficult to dispute the importance of, and need for high quality, credible, easy-to-access, and unbiased drug information. Although “easy access” to drug information sources does not appear to be an issue with the plethora of handheld and tablet devices (as well as desktop and laptop computers), questions of “cost to access” and “credibility of access” must be kept in mind.

There are numerous high-quality, unbiased sources of information that can be accessed for free. However, many of these sites offer limited functionality, such as the posting of abstracts of journal articles, with the more clinical components only accessible through a paid subscription. While abstracts can be helpful, they often omit most, if not all, of the clinical commentary and possible limitations to a recent study. In these cases, information gleaned from an abstract might be incomplete and out of context could possibly lead to more harm than good for the patient. Other “free” drug information sources are funded through sponsorships from organizations with vested interests in the drugs posted, and some sites are linked directly to the manufacturer. In both cases, questions of bias are introduced – and whether this bias is real or perceived, one might never be sure as to the authenticity and credibility of posted reports and recommendations.

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A paid subscription to a drug information service is a difficult concept to sell when an alternate and seemingly equivalent option is available for free. When dealing with commodities, one might be willing to take a chance on the free service, particular if the risks are minimal (if not completely absent). However, drug information is not a commodity, and accuracy and authenticity in its provision is critical – the alternative can mean misinformation and can have dire consequences in terms of patient outcomes.

SUMMARY:

It is the position of the Ontario Pharmacists Association and its Drug Information and Resource Centre that the DPRA and OCP Library Requirement requiring that a pharmacy maintain a mandatory drug information service be upheld and protected. Furthermore, insofar as many other health professions outside of pharmacy are experiencing expansions in scopes of practice that would enable them to prescribe and/or dispense medications, it is the opinion of the Association that all such practitioners be required under their own regulations and standards of practice to maintain a drug information subscription in the same manner as pharmacies.

Protection of the patient is paramount when it comes to the prescribing and dispensing of medications. In most cases, pharmacists are patients' last bastion of protection before a medication is administered. It is therefore with the best interests of patients in mind that every precaution remains in place to ensure healthcare providers have access to as much information as possible to optimize therapy and mitigate, if not avoid completely, any negative consequences. The currently mandated subscription service model constitutes an important patient safety net and is an efficient and cost-effective approach for pharmacists to obtaining credible, unbiased drug information at their places of practice.

Should you have any questions in regard to this position paper, please do not hesitate to contact me at 416-441-0788 at your earliest convenience.

Yours truly,



Allan H. Malek, B.Sc(Bio)(Pharm)
Senior Vice President, Professional Affairs

cc: Dennis A. Darby, Chief Executive Officer, Ontario Pharmacists Association
Deb Saltmarche, Chair of the Board, Ontario Pharmacists Association
Marshall Moleschi, Registrar, Ontario College of Pharmacists
Tina Perlman, Manager, Pharmacy Practice, Ontario College of Pharmacists



APPENDIX A

SAMPLES OF DIRC QUESTIONS & RESPONSES FROM 2014 (de-identified)

Physician-initiated Question to a Community Pharmacist: A physician contacts the community pharmacy with a question regarding one of his female patients. She had been diagnosed with polycystic ovarian syndrome (PCOS) and has a family history of breast cancer, heart disease and migraines. Frustrated with her irregular periods, the patient has asked her doctor about the use of birth control pills which she heard can be helpful. Given the patient's medical history, the physician is now looking to his patient's community pharmacist for assistance in finding therapeutic options for this unique but confounding scenario.

SUMMARY OF RESPONSE:

The treatment of PCOS requires many different drugs but if the caller is looking for a hormonal treatment then intermittent progesterone, daily progesterone and progestin-releasing intrauterine device (IUD) may be used.

REFERENCES:

Patient with PCOS has irregular periods and is looking for birth control methods for irregular periods but the patient's mother has:

- a history of breast cancer and has a condition for which there is no restriction for the use of the contraceptive method.
- parents have a history of heart disease and has condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- migraines - what are her options ?

UpToDate (v.18.1), Waltham, MA, 2010

- Treatment of polycystic ovary syndrome in adults
- Menstrual dysfunction
- Endometrial protection — The chronic anovulation seen in polycystic ovary syndrome (PCOS) is associated with an increased risk of endometrial hyperplasia and possibly endometrial cancer.

Choice of Oral Contraceptive

- We typically start with an oral contraceptive containing 20 mcg of ethinyl estradiol combined with a progestin with minimal androgenicity (such as norgestimate). Other progestins with minimal androgenicity or antiandrogenic properties include desogestrel and drospirenone, but both have been associated with a possible higher risk of venous thromboembolism. OCs containing one of the original progestins, norethindrone or norethindrone acetate, are also good options; while they are not as low in androgenicity, they have not been associated with excess venous thromboembolism (VTE) risk. (See "Risks and side effects associated with estrogen-progestin contraceptives", section on 'Type of progestin'.)
- Higher doses of ethinyl estradiol (30 to 35 mcg) are needed in some women for optimal suppression of ovarian androgens and management of hyperandrogenic symptoms
- Combined estrogen-progestin contraceptives provide a number of benefits in women with PCOS, including:
 - Daily exposure to progestin, which antagonizes the endometrial proliferative effect of estrogen
 - Contraception in those not pursuing pregnancy, as women with oligomenorrhea ovulate intermittently and unwanted pregnancy may occur
 - Cutaneous benefits for hyperandrogenic symptoms (see 'Androgen excess' below)
- Oral contraceptives affect insulin sensitivity, carbohydrate metabolism, and lipid metabolism; the effects depend upon the estrogen dose and androgenicity of the progestin. However, there is no evidence that women with PCOS are at greater risk for either metabolic adverse effects or cardiovascular complications of oral contraceptives
- Metformin is a potential alternative to restore menstrual cyclicity, as it restores ovulatory menses in approximately 30 to 50 percent of women with PCOS [4,5]. Its ability to provide endometrial protection is less well established, and we therefore consider it to be second-line therapy [6,7]. (See "Metformin for treatment of the polycystic ovary syndrome".)



- When metformin is used, we suggest monitoring to confirm that ovulatory cycles have been established. This can be done with luteal phase serum progesterone measurements or transvaginal ultrasound. (Se

US Medical Eligibility Criteria for Contraceptive Use: Summary of classifications for hormonal contraceptive methods and intrauterine devices

- Family history (first-degree relatives)
 - A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

Alternatives to oral estrogen-progestin contraceptives include cyclic progestin therapy, continuous progestin therapy (progestin-only oral contraceptives [the “minipill”]), or a progestin-releasing intrauterine device (IUD). Cyclic progestin therapy can induce regular withdrawal uterine bleeding and reduce the risk of endometrial hyperplasia. Both continuous progestin therapy (eg, a progestin-only oral contraceptive such as norethindrone 0.35 mg/day) and the progestin-releasing IUD provide contraception and reduce the risk of endometrial hyperplasia

- <http://www.aafp.org/afp/2009/0415/p671.html>
- American Family MD: Drug Treatments for Polycystic Ovary Syndrome

UpToDate (v.18.1), Waltham, MA, 2010: Risks and side effects associated with estrogen-progestin contraceptives

- Data on breast cancer risk in OC users with a family history of breast cancer are also conflicting. In one case-control study [89], the risk was not increased in women with a family history of breast cancer [89]. In contrast, a review of women taking OCs prior to 1975 (high dose formulations) found an increase in breast cancer risk in those who had a first-degree relative with breast cancer (RR 3.3, 95% CI 1.6-6.7) [94]. However, the small number of breast cancer cases and the high dose formulations used prior to 1975 limit the generalizability of this report to current OC use.
- WHO [137] and ACOG conclude from the literature that women with a history of migraine headaches who take oral contraceptives are at increased risk for cerebral thromboembolism, and that the risks of OC use usually outweigh the benefits in women over age 35 years with migraines. In addition, they suggest that for women of any age with migraines associated with aura or focal symptoms, the risk of OC use is unacceptable. (See "Headache, migraine, and stroke", section on 'Migraine and ischemic stroke risk'.)
 - In women with migraines without aura, other modifiable risk factors for stroke such as smoking, hypertension, and dyslipidemia should be identified and treated before considering using an OC [138,139].
 - Approximately 25 percent of women with migraine headaches have auras, which are usually visual. The International Headache Society's definition of aura is reviewed separately. (See "Pathophysiology, clinical manifestations, and diagnosis of migraine in adults".)
 - In women with migraines with aura but no other risk factors, the frequency and severity of the aura is likely to be important. For example, a patient who experienced only one to two aura in the distant past may be a reasonable candidate for an OC, while a patient who experiences a prolonged aura with every migraine would not be.

Pharmacist-initiated Question to DIRC Regarding a Complex Prescription: A patient has presented his pharmacist with a prescription requiring a formulation that is not readily available. The pharmacist contacted numerous places to locate the desired formulation but with no success and is now seeking assistance from DIRC on a recipe in the literature for compounding purposes.

SUMMARY OF RESPONSE:

Pharmacist confirmed from his wholesaler that Clindasol which has sunscreen ingredients as well as clindamycin has been discontinued. Pharmacist is not interested in information from eDocs (Dormer), wants formulation with clindamycin powder. DIRC consulted with pharmacy department at Sunnybrook...informed that they simply incorporate clindamycin powder in Glaxal Base to provide a 1% cream. Pharmacist still wanted DIRC to find a formulation i.e from Medisca, etc.

- Spoke to XXXXX at Medisca, provided phone number: 1.800.665.6334 ext XXXX
 - They have one formulation using Medisca Versapro cream base and clindamycin phosphate powder, also has tretinoin in it but pharmacist can modify the formulation to exclude the tretinoin



- DIRC advised to have the pharmacist contact Medisca directly and they can discuss the formulation with the pharmacist and provide it
- Pharmacist said he will call Medisca to discuss this formulation to see if it would be appropriate for him as something to consider; he had also contacted the previous pharmacy where the prescription was transferred from and received information from them on how to make this product

REFERENCES:

- 1) Drug Product Database
 - Only vaginal cream and topical solutions found
 - DALACIN VAGINAL CREAM
 - Clindamycin Phosphate Vaginal Cream (20 mg clindamycin/g)
 - Vaginal Antibacterial Preparation, Pfizer Canada Inc
 - CLINDA-T
 - Clindamycin Phosphate Topical Solution USP (equivalent to 1% w/w Clindamycin in solution)
 - Antibiotic, Valeo Pharma Inc. Date of preparation:
- 2) e-CPS
 - Clindasol®
 - clindamycin phosphate—octinoxate—avobenzone
 - Acne Therapy, Stiefel (GSK)
 - DIN(s):02242970
- 3) www.ijpc.com
 - no info
- 4) eDOCs
 - 20375
 - Compound with Dormer products
- 5) QADB (internal DIRC database)
 - No info
- 6) Trissels Stability of Compounded Formulations 4th Edition
 - Clindamycin p. 141-144
 - No info
- 7) IWK, CHEO, Sick Kids, Nahata Pediatric Drug Formulations 6th Edition, Alberta Health Services Compounding Manual December 2013
 - No info
- 8) Princess Margaret Hospital, General Inquiries, 416 946 2000, inpatient pharmacy
 - Spoke to XXXX who said they don't use clindamycin cream there
- 9) Sunnybrook Health Sciences Centre, 2075 Bayview Ave, Toronto, (416) 480-4513
 - Spoke to pharmacist XXXX who said he will email me some information and I can pass this on to the pharmacist who inquired
 - Response by email from XXXX: "We simply incorporate clindamycin powder in Glaxal Base to provide a 1% cream".
- 10) Sick Kids Compounding, 416-813-670, left message.
 - XXXX called back from Sick Kids and said she does not compound clindamycin 1% cream, does not have a formula



11) Medisca, 1.800.665.6334 ext XXXX

- Left message for XXXXX at extension XXXX
- Medisca called back next day
 - Have one formulation using Medisca Versapro cream base and clindamycin phosphate powder, also has tretinoin in it but pharmacist can modify the formulation to exclude the tretinoin
 - Please have pharmacist contact them directly and she can discuss the formulation with the pharmacist and provide it
 -

Pharmacist-initiated Question to DIRC Regarding Accidental Overdosing: A patient has called her pharmacist saying she has inadvertently taken a double dose of five medications and wants to know if she is in any imminent danger and what she should look out for. The pharmacist has recognized that while this question is directly answerable, it would take considerable time and she is the only pharmacist on duty in a busy pharmacy. Because of the time-sensitivity of the response, the pharmacist is asking DIRC for assistance while she continues to provide care to her other patients.

SUMMARY OF RESPONSE:

- Plavix has been used in loading doses of 300mg
- Atacand has been studied in doses of 64mg - not usual dose as there is no greater efficacy above 32mg - dizziness
- HCTZ has been Rx'd at doses of 50mg - dizziness
- Norvasc no info above 10mg daily - watch for dizziness/headache
- Pravastatin has been used at 40mg daily
- Ezetrol 10mg- no info

REFERENCES:

MICROMEDEX (R): DRUGDEX (R) System [intranet database]. Version 5.1. Greenwood Village (CO): Thomson Reuters (Healthcare) 2011. Available from: www.micromedex.com.

Clopidogrel

UpToDate (v.18.1), [Internet Database] Waltham, MA, 2011

Clopidogrel: Drug information

- ST-segment elevation myocardial infarction (STEMI): receiving fibrinolytic therapy (in combination with aspirin and appropriate anticoagulant) (O'Gara, 2013): Note: If patient is to undergo primary PCI, see Percutaneous coronary intervention (PCI) for acute coronary syndrome dosing.
- Age ≤75 years: Loading dose of 300 mg followed by 75 mg once daily for at least 14 days up to 1 year (in the absence of bleeding)

UpToDate (v.18.1), [Internet Database] Waltham, MA, 2011

- Candesartan and hydrochlorothiazide: Drug information: Dosing: Adult
 - Hypertension, replacement therapy: Oral: Combination product can be substituted for individual agents; maximum therapeutic effect would be expected within 4 weeks
 - Usual dosage range:
 - Candesartan: 8-32 mg daily, given once daily or twice daily in divided doses
 - Hydrochlorothiazide: 12.5-50 mg once daily

MICROMEDEX (R): DRUGDEX (R) System [intranet database]. Version 5.1. Greenwood Village (CO): Thomson Reuters (Healthcare) 2011. Available from: www.micromedex.com.

CANDESARTAN CILEXETIL DRUGDEX® Evaluations

- b) There was no significant difference between 16 mg once-a-day and 8 mg twice-a-day administration in efficacy and incidence of adverse events [29]. The 64 mg dose did not provide any additional benefits

UpToDate (v.18.1), [Internet Database] Waltham, MA, 2011

Ezetimibe: Drug information: Dosing: Adult

- Hyperlipidemias, sitosterolemia: Oral: 10 mg/day



MICROMEDEX (R): DRUGDEX (R) System [intranet database]. Version 5.1. Greenwood Village (CO): Thomson Reuters (Healthcare) 2011. Available from: www.micromedex.com.

EZETIMIBE DRUGDEX® Evaluations

- No info above 10mg
- Adverse Reactions Significant
 - 1% to 10%:
 - Central nervous system: Fatigue (2%)
 - Gastrointestinal: Diarrhea (4%)
 - Hepatic: Transaminases increased (with HMG-CoA reductase inhibitors) ($\geq 3 \times$ ULN, 1%)
 - Neuromuscular & skeletal: Arthralgia (3%), pain in extremity (3%)
 - Respiratory: Upper respiratory tract infection (4%), sinusitis (3%)
 - Miscellaneous: Influenza (2%)

UpToDate (v.18.1), [Internet Database] Waltham, MA, 2011

- Amlodipine: Drug information: Dosing: Adult
 - Hypertension: Oral: Initial dose: 5 mg once daily; maximum dose: 10 mg once daily. In general, titrate in 2.5 mg increments over 7-14 days. Usual dosage range (JNC 7): 2.5-10 mg once daily.
 - Angina: Oral: Usual dose: 5-10 mg; most patients require 10 mg for adequate effect.

MICROMEDEX (R): DRUGDEX (R) System [intranet database]. Version 5.1. Greenwood Village (CO): Thomson Reuters (Healthcare) 2011. Available from: www.micromedex.com.

- AMLODIPINE DRUGDEX® Evaluations
 - No info

MICROMEDEX (R): DRUGDEX (R) System [intranet database]. Version 5.1. Greenwood Village (CO): Thomson Reuters (Healthcare) 2011. Available from: www.micromedex.com.

- Pravastatin Sodium Adult Dosing Information
 - Cerebrovascular accident, Reduction of risk
 - 1) initial, 40 mg ORALLY once daily
 - 2) maintenance, 40 mg to 80 mg ORALLY once daily
 - Coronary arteriosclerosis, Primary; Prophylaxis
 - 1) initial, 40 mg ORALLY once daily
 - 2) maintenance, 40 mg to 80 mg ORALLY once daily
 - Coronary arteriosclerosis, Secondary; Prophylaxis
 - 1) initial, 40 mg ORALLY once daily
 - 2) maintenance, 40 mg to 80 mg ORALLY once daily
 - Hyperlipidemia
 - 1) initial, 40 mg ORALLY once daily
 - 2) maintenance, 40 mg to 80 mg ORALLY once daily