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Dear Ms Stevenson

RE: The Canadian Pharmacists Association Response to Proposed Regulation Changes under the *Drug Interchangeability and Dispensing Fee Act (DIDFA)*

Introduction

The Minister of Health and Long-Term Care has extended an invitation for public comments on the proposed changes to the DIDFA regulations. The Canadian Pharmacists Association (CPhA) recognizes that comments made in reference to the proposed changes may be made public in the ordinary course of evaluating and revising the proposed regulations.

CPhA is the national, voluntary organization of pharmacists, committed to providing leadership for the profession and improving the health of Canadians.

Prior to addressing the regulations, CPhA would like to reiterate that all pharmacists support the values that the Minister has espoused, namely “to deliver the highest quality care for patients; to ensure the sustainability of our health care systems; to be accountable for public finances; and to stand up for the most vulnerable”.

CPhA would like to comment on the following sections of the proposed regulation changes.

Summary of proposed regulations changes to amend the DIDFA Regulations

Section 1

CPhA notes that the change to section 1(3) of the DIDFA Regulation eliminates the opportunity for a pharmacy to charge less for a drug product than the drug benefit price published in the Formulary. As the revoked section permitted predatory activity by certain pharmacies that could harm the viability of other pharmacies in the same market, this change is clearly a positive one, both for the pharmacy profession and for patients. The revoked section had the potential for allowing competitive forces that could ultimately limit patient choice.



Section 2

CPhA notes that the cap on professional allowances for interchangeable products not reimbursed under the Ontario Drug Benefit Act is an unprecedented change to the regulations that will significantly impact the financial viability of pharmacies in Ontario. As Grootendorst¹, a respected health economist, clearly described in his paper prepared for the Competition Bureau, these allowances have been created in response to successive policies of the Ontario government, since the introduction of the Ontario Drug Benefit (ODB) program. The Ontario government has further compounded the issue by failing to significantly increase the professional fee for pharmacists for services provided to ODB. Both the government and private payers have been content to have generic manufacturers subsidize the provision of pharmacy services for the past 20 years.

As outlined, the proposals for reform will have a negative effect on people in Ontario. In 2003, the government in South Africa introduced a similar scheme that eliminated all forms of rebates and discounts and failed to properly provide replacement funding for pharmacies. As a consequence, over 500 community pharmacies closed.

At best, in Ontario, the public will experience significant reductions in access to pharmacists and will have to pay for services that are currently funded through the regulation of professional allowances, introduced by your government in 2006.

This amendment would impact all pharmacies, with a greater impact felt by pharmacies whose business model relies heavily on cash paying patients or patients with third party insurance. It would also impact smaller independent pharmacies, whose main source of revenues is prescription medication. As such, this regulation change may have a disproportional impact on rural pharmacies, in spite of the higher professional fees and markups afforded these pharmacies.

The payment model of the non-ODB market has for many years supported pharmacies at a time when their costs have not been recovered with respect to dispensing ODB prescriptions. While pharmacists in general lament this model, the fact that reimbursement from the Ontario Drug Benefit Program has failed to keep up with inflation has resulted in this inequity. It appears inevitable that many pharmacies will be forced to charge a higher dispensing fee in this situation. The inevitable consequences for patients will be reduced access to services and more out of pocket expenses to pay for services.

CPhA recommends that ordinary commercial terms should be separate of any professional allowance provisions. CPhA also recommends that there should be no cap to ordinary commercial terms, but instead, market forces should prevail in their determination. Commercial terms should be extended to single source medications.

Section 5

CPhA notes that this section imposes restrictions in two areas. Firstly, it will limit the number of generic versions of a given molecule by restricting cross-licensing of these products. We anticipate that this regulation change, together with the pricing changes affecting generic manufacturers, may result in a consolidation in the generic pharmaceutical industry, particularly impacting the smaller firms. Currently there is a significant problem with frequent shortages of generic pharmaceuticals. Restrictions on cross licensing could lead to a worsening of shortages. This could also result in fewer generic versions being made available as products come off patent. This could have a



detrimental effect on any reductions in expenditures that could be achieved through more generic products entering the market.

The second stakeholder impacted by this regulation change is the pharmacy operator that chooses to manufacture its own line of generic products. As far as we are aware, there is only one pharmacy operator in Ontario that has indicated the desire to manufacture generic products (i.e., Shoppers Drug Mart); this regulation change is no doubt targeted to this corporation. CPhA is of the opinion that this regulation change is unnecessarily punitive, given that the decision of this corporation to manufacture generic drug products is budget neutral to the Province of Ontario, and that Health Canada must approve all products prior to market. This regulatory change is also in contrast to the European market, where attempts by organizations to extend their role in the production or distribution of pharmaceuticals, through vertical integration, appear to be supported by the European Commission.

CPhA feels that this policy is misconceived, and fails to acknowledge the positive effect of vertical integration initiatives that have occurred in the European Union. Vertical integration in this region has been shown to improve the value chain by offering both operational and cost efficiencies. One of the best known examples of vertical integration in this industry within the EU is Alliance Boots GmbH, with both a significant network of pharmacies and a manufacturing base. It should also be noted that within the last few years, there have been significant supply disruptions with respect to generic pharmaceuticals; it seems that simplifying the supply chain would only improve the availability of medication. Therefore, the benefits of hindering vertical integration in Ontario seem ill-conceived. We oppose this regulatory change, since it is not in the interest of patients or the health care system.

Summary of proposed regulation to amend the ODBA Regulation

Section 4

CPhA notes that provisions that impact the continuity of drug supply must be considered cautiously, given the potential to adversely impact the health of Ontario citizens. Similarly, the prohibition against price increases (i.e., limited to once every five years for single source or exempted older products) does not appear realistic, and may impact the availability of drug products.

Section 5

The proposed changes to allowable markups and dispensing fees must also consider the total prescription volume, not only the prescription count for patients covered by Ontario Drug Programs. The proposed step-wise changes to dispensing fees are insufficient to offset the significant impact of eliminating professional allowances. In order to operate under the proposed funding model, higher dispensing fees must be implemented. The widely recognized funding gap that exists between the cost of providing services and the fee paid implies that pharmacies cannot be viable unless fees are increased appropriately. More work is needed in this area and we encourage the government to partner with pharmacy organizations to ensure that fees are set at levels that ensure the financial viability of pharmacies.



Other CPhA Comments

CPhA is disappointed with the proposed changes that the Minister has put forward. It appears that efforts on behalf of pharmacy organizations to engage the Ministry and identify a solution to the budget shortfall have been to no avail. The outcome is regrettable, and the consequences to both patients and the pharmacy profession will be substantial.

There are other options. First, lower generic drug prices and a system of professional allowances for pharmacy are not incompatible. The best current example is in Britain. Generic prices are among the lowest in the world. This has been achieved by government and pharmacy working together, where the contract is structured in such a way as to incent pharmacists to buy generics at a low price and retain some of the savings. This so-called “retained medicine margin” scheme was recently reported upon favourably by the National Audit Office² in Britain, citing savings of £1.8 billion and increasing pharmacy productivity by 8 per cent.

The proposed increases in funding fall far short of the funds being removed from community pharmacies. It should also be noted that the proposed changes have reverberated across the country, with the potential for similar policy decisions in other jurisdictions. This change in policy is coming at a time when the pharmacy profession, working with governments and regulatory authorities, is assuming expanded scope activities that offer both an enhanced patient focus and a cost-effective means of performing activities that in the past were performed by physicians or other health care professionals. These expanded scope activities are significant changes in the way pharmacy is practiced, and while data is in the process of being compiled in jurisdictions where expanded scope is a reality, it appears that patients will ultimately accrue significant benefits. It also appears short-sighted to jeopardize these activities, not to mention those activities that pharmacists have been providing for many years, such as patient counseling. The regulatory changes have the potential to reduce pharmacist activities to a more distribution-focused role, due to a likely contraction in the pharmacist workforce, a direct result of these changes.

Since 2006, the Canadian Pharmacists Association has led a major national initiative to prepare pharmacy for the future. The Blueprint for Pharmacy³ initiative has been supported by 78 pharmacy organizations, including the Ontario Pharmacists’ Association, the Ontario College of Pharmacists and all of the large pharmacy chains. Reform is needed in pharmacy human resources; legal regulation and liability; education and training; the adoption of information technology; and most importantly, these developments must take place in a framework that maintains the financial viability and sustainability of pharmacies. The Blueprint for Pharmacy Implementation Plan⁴ outlines a pan-Canadian, collaborative strategy to facilitate the changes required to align pharmacy practice, including the reimbursement model for community pharmacy, with the health care needs of Canadians.

The widespread adoption of an expanded scope of practice for both pharmacists and pharmacy technicians is needed to achieve the Vision for Pharmacy, Optimal Drug Therapy Outcomes through Patient-centred Care. This is predicated upon a change in the compensation model for professional pharmacy services. Thus, your public statements to provide additional funds for new professional services is very welcome and is a step in the right direction, but it will not work if the other proposals completely undermine the existing funding model. CPhA recommends that the government amends the proposed regulations to support pharmacists financially through this



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period of change. This could take the form of additional increases in dispensing fees or by phasing in the withdrawal of professional allowances.

The sustainability of health care in this province, and indeed the nation, is a concern not only of provincial governments, but also of all us who work in health care, including pharmacists. As a health care association, we recognize the need for reform of the drug system. We have been strong supporters of the need for a National Pharmaceutical Strategy and have been disappointed at the failure of the FPT process to make progress on this initiative. We have also advocated that generic prices should be regulated through a scheme similar to the Patented Medicine Prices Review Board. We are all aware of how escalating health costs are eroding the ability of provincial governments to allocate resources to other ministries, and in fact to meet their budgetary requirements. As our nation's population ages and the demographic profile is altered, these challenges will become even more profound. The pharmacy profession has made attempts to engage health ministries to offer potential solutions, from its perspective, to mitigate these challenges. On the basis of the proposed regulatory changes, it appears that the chosen solution, while politically expedient, has failed to consider the value proposition that pharmacy can offer the health care system.

In relation to stakeholder engagement with respect to these regulation changes, CPhA feels that the time between the deadline for public comment (i.e., May 8th) and the date when the proposed changes can be implemented (i.e., May 15th) is insufficient to allow for adequate consultation and dialogue. If the Ministry wishes to engage in a fulsome dialogue in order to facilitate the implementation of health care reform and engage its health professionals, it is vital that the time and effort applied to this process be appropriate.

In summary, the people of Ontario value and respect the high quality services they receive from their community pharmacists. Government and pharmacy must work together if we are to maintain this high-quality of care and ensure that we will have a viable and sustainable health care system that meets the needs of future generations. Now is the time to re-engage the pharmacy profession in identifying a superior solution that will result in a win-win, rather than enacting regulations that will clearly significantly reduce patient access to pharmacy services.

Sincerely,

Jeff Poston, PhD., MRPharmS.
Executive Director
Canadian Pharmacists Association

¹ http://individual.utoronto.ca/grootendorst/pdf/Grootendorst_et_al_Pharmacy_Rebates_Report_Final.pdf

² http://www.nao.org.uk/publications/0910/community_pharmacy.aspx

³ www.pharmacists.ca/blueprint

⁴ http://www.pharmacists.ca/content/about_cpha/whats_happening/cpha_in_action/pdf/BlueprintImplementationPlan.pdf