CMA response:

HEALTH CANADA CONSULTATION ON RESTRICTION OF MARKETING AND ADVERTISING OF OPIOIDS

July 18, 2018

ASSOCIATION MÉDICALE CANADIENNE

CANADIAN MEDICAL ASSOCIATION

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, the CMA's mission is to empower and care for patients and its vision is to support a vibrant profession and a healthy population.

On behalf of its more than 85,000 members and the Canadian public, the CMA performs a wide variety of functions. Key functions include advocating for health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and over 60 national medical organizations.

The Canadian Medical Association (CMA) is pleased to provide this submission to Health Canada in response to the publication of the Notice of Intent to restrict the marketing and advertising of opioids.[1] The CMA is very concerned with the high rates of overdose deaths due to opioids[2] and supports a comprehensive, multi-pronged approach to address this public health crisis.[3]

As part of the Government of Canada's strategy, the Minister of Health's 2017 mandate letter committed to "consult with provinces, territories, and professional regulatory bodies to introduce appropriate prescribing guidelines to curb opioid misuse, ensure prescriptions are appropriately tracked in a consistent and patient-centred way, and increase transparency in the marketing and promotion of therapies."[4] Health Canada is proposing to further restrict drug manufacturers' advertising of opioids and is consulting on the scope and intent of the restrictions. The Food and Drugs Act defines advertisement as "any representation by any means for the purpose of promoting, directly or indirectly, the sale of any drug or device".[5]

Opioids are important therapeutic tools and serve legitimate purposes, when prescribed in an appropriate manner with proper assessment, and as part of a comprehensive therapeutic strategy and monitoring. These medications have been essential in areas such as palliative and cancer care and have contributed to the alleviation of suffering.[3] Any measures to address advertising must not restrict appropriate access. Limiting access without appropriate alternatives and careful tapering can lead to undue suffering and seeking of drugs, potentially tainted, on the illegal market.

However, of great concern, opioid dispensing levels have been shown to be strongly correlated with increased mortality, morbidity and treatment admissions for substance use.[6,7] Many patients were prescribed these medications and developed dependence.[8]

Since the 1990s, opioids have been recommended for longer-term treatment of chronic non-cancer pain, and have become widely used due in part to aggressive promotion and marketing for this indication.[9,10] However, there is evidence for pain relief in the short term but insufficient evidence regarding maintenance of pain relief over longer periods of time, or for improved physical function.[11,12,13] There was also a concerted effort by industry to minimize the risk of addiction in the use of opioids for the treatment of chronic non-cancer pain. While stating that the risk of addiction was less than one percent, many studies have shown that the risk varies from 0 to 50% depending on the criteria used and sub population studied.[14] Marketing significantly influences the type and amount of opioids consumed.[15] Substantial tension exists between the competitive pressures that manufacturers face to expand product sales and support for limited, evidence-based use of most cost-effective available alternatives.[16]

Choices made by prescribers are subject to a number of influences, including education (undergraduate, residency and continuing); availability of useful point of care information; drug marketing and promotion; patient preferences and participation, and drug cost and coverage.[17] Important contributing factors for the increase in opioid prescriptions are also the lack of supports and incentives for the treatment of complex cases, including availability and funding for treatment options for pain and addictions. Alternate approaches to pain management require more time with patients. Prescriptions also increased due to the availability of new, highly potent opioid drugs.[18,19] Addressing advertising is only one component of the issue, and significant efforts need to be made to address issues such as access to alternatives for pain management and treatment of addiction.

Presently, advertising of opioids is prohibited to the public, and only permitted to health care professionals if the claims are consistent with the terms of market authorization by Health Canada. Pharmaceutical industry's marketing practices to health care practitioners "can take many forms of direct and indirect activities and incentives, including, for example, manufacturer-sponsored presentations at conferences, continuing education programs, advertisements in medical journals, and personal visits from sales representatives. It can also include use of promotional brochures, fees for research, consulting or speaking, reimbursement for travel and hospitality expenses to attend industry-sponsored events, and gifts of meals, equipment, and medical journals and texts."[1] As well, industry has sponsored advocacy organizations dedicated to the treatment of pain and key opinion leaders.[15,20] Studies have shown that marketing influences prescribing patterns.[21]

Initiatives to regulate advertising and the promotion of prescription drugs have come from industry, nongovernmental organizations and government. The pharmaceutical industry itself is voluntarily self-regulated in

Canada through the Pharmaceutical Advertising Advisory Board (PAAB), pre-clearing marketing initiatives based on a Code of Advertising.[22] The CMA recommends that marketing initiatives could be vetted for accuracy and truthfulness through a pre-clearance mechanism such as PAAB.

Faced with multiple legal challenges in the U.S., some opioid manufacturers have limited marketing, however, such measures had not been taken in Canada. The federal government has a complaints-based system and hasn't been proactive in the regulation and monitoring of advertising and marketing of opioids.

In recently published regulations amending the Food and Drug Regulations,[23] the Minister of Health can require companies to develop and implement risk management plans, which include the preclearance of opioid-related materials to be provided to health care professionals. Product information prepared by manufacturers, summarizing scientific evidence on effects and setting out conditions for use, as well as promotional activities are subject to regulatory approval. The authority conferred to the Minister has the objective of allowing Health Canada to "appropriately monitor, quantify, characterize, and mitigate the risks associated with post-market use" of opioids. CMA supports such actions. As Van Zee has noted in the case of the United States, "modifications of the promotion and marketing of controlled drugs by the pharmaceutical industry and an enhanced capacity of the Food and Drug Administration to regulate and monitor such promotion can have a positive impact on public health".[14] This approach would confer a similar benefit for Canada in that, if effective, could contribute to unbiased, evidence-based prescribing.

There are important guidelines and standards in place, developed by physicians, to guide relationships with the pharmaceutical industry. CMA's "Guidelines for Physicians in Interactions with Industry"[24] were developed as a resource tool both for physicians, medical students and residents, as well as medical organizations, to support decisions as to appropriate relationships with industry, in conjunction with CMA's Code of Ethics.[25] In summary, physicians have a responsibility to ensure that their interaction with the pharmaceutical industry is in keeping with their primary obligation to their patients and duties to society, and to avoid situations of conflict of interest where possible, appropriately managing these situations when necessary.

These guidelines include principles for continuing medical education and continuing professional development (CME/CPD) and are the basis for the National Standard for Support of Accredited CPD Activities, developed by the Royal College of Physicians and Surgeons of Canada (RCPSC), the College of Family Physicians of Canada (CFPC) and the Collège des médecins du Québec. According to the Standard, "the interests of organizations that provide financial and in-kind support for the development of accredited CPD activities cannot be assumed to always be congruent with the goal of addressing the educational needs of the medical profession. Therefore, it is essential that the medical profession define and assume their responsibility for setting standards that will guide the development, delivery, and evaluation of accredited CPD activities."[26] Physicians must complete CPD credits to maintain their professional license, and the accreditation bodies (such as CFPC, RCPSC) have processes in place to assure that these courses are evidence-based and free from industry bias.

In recognition of the importance of opioid prescribing, and the key role that physicians play in this field, the CMA recommends that the government fund certified / accredited CPDs on pain management addressing non-pharmacologic and pharmacologic options, including opioids. This funding could include unconditional contribution from the opioid manufacturers, to ensure independence. The CMA appreciates the role that Health Canada has had in funding evidence-based guidelines.[27] This has been a key initiative, which sought to provide physicians with unbiased information. Ongoing funding to maintain their currency would be warranted.

The CMA supports long overdue actions related to the restriction of the marketing of opioids and looks forward to collaboration between Health Canada and the physician community.

Recommendations

The CMA supports Health Canada's efforts to place significant restrictions on the ability of drug manufacturers to advertise opioids to health care practitioners. Marketing initiatives should be vetted for accuracy and truthfulness through a pre-clearance mechanism.

The CMA recommends that the measures chosen to constrain advertising do not unduly restrict access to opioids for appropriate use.

The CMA recommends that the government fund certified / accredited CPDs on pain management addressing non-pharmacologic and pharmacologic options, including opioids, and consider unconditional funding from opioid manufacturers.

The CMA recommends that the government support keeping the 2017 Opioid Prescribing Guidelines current through ongoing funding.

The CMA recognizes that restricting advertising is only one, overdue, measure to address the opioid crisis, and recommends that issues such as access to alternatives for pain management and addiction treatment urgently be addressed.

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