Canadian Paediatric Society
Société canadienne de pédiatrie

Written Submission to the Health Canada Consultation: Adding melatonin for sleep-related use in the pediatric population to the Prescription Drug List

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Introduction

The Canadian Paediatric Society (CPS) is pleased to submit the following comments as part of Health Canada's public consultation: "Adding melatonin for sleep-related use in the pediatric population to the Prescription Drug List".

As Canada's national association of paediatricians, paediatric subspecialists and other child and youth health providers, the CPS appreciates Health Canada's recognition of the importance of healthy sleep for all children and young people's physical and mental health and development, well-being and optimal functioning. Supporting families to engage with health care providers to discuss sleep concerns and avoiding unintended consequences of exposure to inconsistent and unregulated quantities of melatonin and potentially harmful additional substances is to be commended.

Importance of healthy sleep

Sleep is a pillar of physical and mental health, along with nutrition and exercise. However, approximately 25% of typically developing children and more than 80% of children with neurodevelopmental conditions will experience sleep disorders[1]. Children with health conditions such as Type 1 diabetes, asthma, eczema, and obesity also experience an increased incidence of sleep disorders. Data from the Canadian Health Measures Survey (CHMS) from 2007 to 2013 suggest that 32% percent of children and 42% of adolescents have trouble going to sleep or staying asleep and 11% of children and 32% of adolescents find it difficult staying awake during the day[2]. Moreover, children's sleep affects parents' sleep, with consequent impacts on their abilities to provide nurturing parenting practices, maintain paid employment and optimise their own physical and mental health.

Poor sleep is known to have an immediate impact on attention, concentration, and efficient learning, including memory consolidation[3]. It also reduces immune function[4] and upsets the usual pattern of hormone release and suppression. Poor sleep increases the likelihood of accidents, and makes people more irritable, anxious, depressed, and less able to cope with pain and daily life challenges[5]. Equally importantly, poor sleep in childhood is a robust predicter of mental and physical health problems in adolescence including suicide risk[6], obesity, and high blood pressure, and is strongly associated with the development of chronic pain syndromes[7].

Importance of health care provider support in optimising healthy sleep

While behavioural insomnia is by far the most common reason for sleep problems, it is important for health reasons to be ruled out or treated. These include conditions such as pain or discomfort, sleep disordered breathing, allergies, low ferritin levels, gastroesophageal reflux, constipation, mood disorders and epilepsy. It is also important to consider whether medications or over-the-counter (OTC) treatments could be contributing to or causing the sleep disturbance. Common examples include attention-deficit hyperactivity disorder (ADHD) medications, selective serotonin reuptake inhibitors (SSRIs), some anticonvulsants, and corticosteroids.

Currently, some parents are accessing and administering OTC melatonin to their children without going through a process that addresses these other potential issues and without receiving sleep psychoeducation that promotes appropriate expectations for sleep according to age, and the adoption of healthy sleep habits and environmental conditions.

Melatonin

Melatonin is the most researched medication for paediatric sleep and the evidence suggests that in short term use it is well-tolerated with no serious side effects[8]. A consistent finding is that melatonin reduces time of sleep onset, with most studies showing an increase in total sleep time and a few studies showing a positive effect on night awakenings[8]. However, it needs to be used correctly to be of benefit. Currently, OTC melatonin is readily available in Canada and is being widely used – often long term - by parents to address children's sleep problems often with little to no guidance on timing, doses and contraindications, or how to use it within a holistic approach to addressing sleep problems.

Rising levels of melatonin support sleep onset, but the effect is lost when peak levels are reached, highlighting the need for appropriate timing of administration and the correct dose. Higher doses can lead to elevated levels of melatonin throughout the 24-hour period, obscuring the important diurnal pattern. The effect of melatonin can be overcome and therefore, using it as an adjunct to behavioural strategies, rather than in isolation, is important[9]. It is also important not to give an additional dose during the night if a child wakes due to its chronobiotic properties. Slow-release preparations more effectively mimic endogenous melatonin release[10].

Concerns about non pharmaceutical grade melatonin

One of the main challenges for safe melatonin use has been the lack of a licensed pharmaceutical grade product in Canada. Concerningly, a Canadian study showed significant variability of melatonin content in melatonin natural health products and the presence of other substances[11]. Melatonin content was found to range from −83% to +478% of the labelled content and the lot-to-lot variable within a particular product was as much as 465%[11]. Variability did not appear to be correlated with manufacturer or product type and Serotonin (5-hydroxytryptamine), was identified in eight (26%) of the supplements[11]. There were similar findings in a recent US study of 25 products; while none contained serotonin, five contained cannabidiol[12].

Caregivers tend to view melatonin as safe due to it being a 'natural' product that is available over the counter, and many feel comfortable increasing doses and altering dosage schedules themselves. The increase in melatonin use and availability in recent years, the variability of content, and lack of concern due to its perception as being natural, are all likely to have contributed to the increase in accidental ingestions in the US since 2012, and the increase in the number of more serious adverse outcomes[13]. Similarly, Canadian poison centres reported an increased number of accidental melatonin ingestions from January 2016 to April 2022, primarily involving children 5 years of age and younger, and a gummy dosage form that can appeal to young children[14].

International Pediatric Sleep Guidelines

In 2024, the International Paediatric Sleep Association published an Expert Consensus Statement with ten recommendations related to children with autism and other neurogenetic disorders[9] and in 2025, they published recommendations relating to typically developing children[15]. Their recommendations include:

- the need for medical supervision
- considering and ruling out other reasons for the sleep disturbance
- using low dosages
- periodically evaluating the ongoing need, and
- discouraging the use of non-verified melatonin products due to variability in unregulated melatonin content compared to label content

Summary

Having licensed pharmaceutical grade melatonin available for the paediatric population will improve the safety of effective management of sleep problems for children and youth who meet the criteria for its use, which should not be restricted to those with autism or specific genetic conditions. Making it a prescription drug will lead to more appropriate intervention for sleep problems.

About the CPS

The Canadian Paediatric Society is committed to working together to advance the health of children and youth by nurturing excellence in health care, advocacy, education, research, and support of its membership. Founded in 1922, the CPS is a voluntary professional association that represents close to 4,000 paediatricians, paediatric subspecialists, paediatric residents, and others who work with and care for children and youth.

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