From:	r r
To:	Medicines Scheduling
Subject:	Public Comments on Interim Decision of Delegate on proposed amendments to Medicines Scheduling for Melatonin [SEC=No Protective Marking]
Date:	Monday, 24 August 2020 5:05:01 PM
Attachments:	public-submission-cover-sheet (5).docx

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With regard to The Interim decision on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #29 March 2020),with respect to Melatonin Re-Scheduling:

1. The required Advisory Statements for Medicine Labels (RASML) statements on *the dosage, formulation, labelling, packaging and presentation of Melatonin include the following statement:*

- ***The dosage of the slow release formulation is 2 mg once daily 1-2 hours before bedtime and after food. This dosage may be continued for up to*** thirteen weeks.
- **2. Similarly, the Product Information recommends dosage up to 13 weeks:**
- **In the literature, it is suggested that long-term safety issues have not yet been established.**

3.For instance, in a 2019 Paper,

- **"Could long-term administration of melatonin to prepubertal children affect timing of puberty? A clinician's perspective"**

  Boafo A, Greenham S, Alenezi S, Robillard R, Pajer K, Tavakoli P, De Koninck J

  Nature and Science of Sleep 2019, 11:1-10
- **concludes as follows:**

it will be important to conduct long-term randomized controlled trials of latency age children and also examine the cellular and systems-level interactions between melatonin and kisspeptin, a recently identified neuropeptide with a locus of action at the gonadotropin releasing hormone neurons that is important in contributing to the timing of puberty onset.

My comments:

I am in favour of the Interim Decision of the Delegate, but I suggest that,in training for pharmacists monitoring the sale of melatonin, it should be emphasised to the consumer, that the recommended duration of use is up to 13 weeks, and that studies to date, have not established the safety of long-term use of Melatonin.

Yours Sincerely,

Ronald Batagol,

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