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NSW Poisons Information Centre
www.poisonsinfo.nsw.gov.au

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Feb 12 2020

Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

Re: Proposed amendments referred for scheduling advice to ACMS #29

The NSW Poisons Information Centre (NSW PIC) provides a phone-based advice service on suspected poisonings to the public and health professionals calling from NSW, TAS and ACT on a near full-time basis and a shared after-hours service to the remainder of Australia. This results in approximately half of Australia's poisons-related calls being received by our Centre.

1.1 Ranitidine

Calls to the NSW PIC regarding exposures to ranitidine have remained constant over the past 6 years, averaging 95 calls per year. Of these calls, 61% related to therapeutic errors. This high percentage of error calls shows patients do not easily understand labelling, and are not aware to seek advice from the pharmacist. We would not support any increase in the quantity of ranitidine available for general purchase (unscheduled) as this would allow such errors to continue for a longer period without opportunity for intervention.

1.3 Fexofenadine

The NSW PIC does not support the current proposal for rescheduling of fexofenadine. Misuse of antihistamine liquids in children under 6 years and for the treatment of cold and flu symptoms continues, despite labelling which advises against such use. Data on the incidence of this has previously been supplied to the TGA. Any unscheduled antihistamine needs to be in a divided preparation (ie NOT a liquid) to prevent this inappropriate use in children under 6 years.

1.4 Flurbiprofen

The proposed scheduling change for flurbiprofen is ambiguous regarding use in children under 12 years. Omission of directions for use in children does not indicate its inappropriateness. We would recommend labelling which advised "Not for use in children under 12 years" to minimise risk of confusion and inappropriate use.

1.5 Ondansetron

The NSW PIC does not support the proposed change to scheduling of ondansetron. The number of calls to the NSW PIC has increased from 22 in 2014 to 79 in 2019, with an average of 25% of patients having symptoms at the time of the call.

1.6 Rizatriptan

The NSW PIC does not support the proposed change to scheduling of rizatriptan. As per information provided for ACMS #28, we regularly receive calls regarding exposures to triptan medications, and although not large in numbers, these calls are very likely to be symptomatic and require medical treatment. Rizatriptan is no different, with over 40% of exposures developing symptoms. The ability of triptans to interact with other medications and existing medical conditions is likely to contribute to this increased incidence of symptomatic adverse reactions and poisoning exposures. Triptans interact with other commonly used serotonergic agents including antidepressants, thereby increasing the risk of serotonin syndrome. Patients suffering migraine are also more likely to be taking other pain medication, including some opiates, particularly tramadol, which can interact with triptans, especially in overdose. Wider availability as a schedule 3 product will see an increased use of triptans in the community and growth in the numbers of adverse reactions and poisoning exposures. The very real possibility exists that these exposures will increase disproportionally to usage as community awareness grows and patients begin self-prescribing. Current regulations which allow for emergency supply to patients who have a clear history of dispensing are sufficient to ensure those patients in need are able to safely access their regular medication in times of need without increasing risk to the community.

1.7 Melatonin

The NSW PIC does not oppose the rescheduling of melatonin to Schedule 3. In acute exposures melatonin is relatively safe with over 61% of exposures being asymptomatic. However, we would like the TGA to be aware of the data we have on exposures, usage and formulation of melatonin when considering scheduling changes.

Calls to the NSW PIC regarding melatonin have increased dramatically over the past 6 years. Many of these calls are regarding products purchased outside of Australia or via the internet.

Year	Calls to NSW Poisons Centre regarding Melatonin
2014	200
2015	270
2016	304
2017	393
2018	506
2019	628

Types of exposures and the age of patients exposed from Jan 2014-Dec 2019 can be seen in the table below. A high percentage of calls are deliberate self-poisoning, particularly in the child and adolescent age group.

Melatonin exposure calls to the NSW PIC Jan 2014-Dec 2019

Call Type / Age	Accidental	Adverse reaction	deliberate-self poisoning	Intentional: other	Other	recreational	Therapeutic Error	Unknown	Grand Total
Neonate (0 to 4 weeks)							1		1
Infant (4 weeks to 1 year)	7						8		15
Toddler (1 to 4 years)	397	3		2	2		122		526
Child (5 to 14 years)	137	5	197	41			350	3	733
Adolescent (15 to 19 years)	5	2	397	39	1	7	48	3	502
Adult (20 to 74 years)	15	23	453	76		5	216	6	794
Elderly (>75 years)	2		4	2			21		29
Unknown			5	1			2		8
Grand Total	563	33	1056	161	3	12	768	12	2608

Our calls indicate there is significant use of melatonin in children, with resultant therapeutic errors, accidental exposures and deliberate self-poisoning in this age group. Much of this use in children is accounted for by compounded products and/or products purchased via the internet. We do not know if these products are being prescribed by an Australian doctor and compliant with regulations.

Many of these products are coming from overseas where the regulations and quality standards for melatonin fall into supplements rather than therapeutic goods and as such, fall below what would be considered appropriate in Australia. It should be noted that of the 768 therapeutic errors, 468 were in children under 15 years and of these, 378 were exposures to products other than the 2mg product. This demonstrates there are a large number of parents using imported products for their children. This could be due to the lack of paediatric friendly and immediate release preparations available locally.

We would recommend the TGA takes into account this widespread use in children when considering any changes in melatonin scheduling. With such extensive use in children already happening, any change which allows a melatonin product to be purchased over the counter is likely to increase usage further, irrespective of the appropriateness of that formulation for children. A scheduling change which includes immediate release or paediatric preparations may fit more with the current usage patterns.

Melatonin exposure calls to the NSW PIC Jan 2014-Dec 2019

Form / Age	Compound formulation	Gummy	Homeopathic	Imported tablet	Liquid	Injection	2mg tablet local	Unknown strength	Grand Total
Neonate (0 to 4 weeks)					1				
Infant (4 weeks to 1 year)				5	10				15
Toddler (1 to 4 years)	6	26	9	183	172		90	40	526
Child (5 to 14 years)	9	23	16	166	200		212	107	733
Adolescent (15 to 19 years)	6		4	80	10		260	142	502
Adult (20 to 74 years)	7	1	9	93	18	2	439	225	794
Elderly (>75 years)					1		27	1	79
Unknown				1	1		1	5	8
Grand Total	28	50	38	528	413	2	1029	520	2608

NB: Imported tablet includes all tablet formulations of melatonin of known strength other than 2mg. This includes 1mg, 3mg, 5mg, 6mg and 10mg tablets/capsules. Some of these products may be accessed via the SAS.

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