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PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS Meeting [November 2019]

Comments by The Pharmacy Guild of Australia to the interim decisions on substances referred to the November 2019 meeting[1].

1. **Sumatriptan**
2. **Zolmitriptan**

Date	5 March 2020
Contact	[redacted]

[1] https://www.tga.gov.au/scheduling-decision-interim/interim-decisions-and-invitation-further-comment-substances-referred-november-2019-acmsaccs-meetings

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1. SUMATRIPTAN

We agree with the Delegate that it would be reasonable to amend the current Poisons Standard in relation to sumatriptan to make the 50 mg formulations Schedule 3 when in a pack containing not more than 2 tablets. We agree that the access controls in place for a Schedule 3 medicine are appropriate and sufficient to mitigate the risk of misuse.

2. ZOLMITRIPTAN

As with sumatriptan we agree with the Delegate that it would be reasonable to amend the current Poisons Standard in relation to sumatriptan to make the 50 mg formulations Schedule 3 when in a pack containing not more than 2 tablets. We agree that the access controls in place for a Schedule 3 medicine are appropriate and sufficient to mitigate the risk of misuse.

We note that the proposed implementation date of the proposed amendment for sumatriptan and zolmitriptan is 1 February 2021 which is not the expected date of 1 June 2020 as outlined in the published timeframes. This we note was decided by the delegate to allow the opportunity for sponsors to adhere to regulatory change and the opportunity to align labelling requirements to be developed and for the development of education and training material to be provided to pharmacists.

We also note that rizatriptan is to be considered at the March 2020 ACMS[2] meeting. We believe that it would make sense that if the Committee and the Delegate are minded to also downschedule rizatriptan then an implementation date of 1 February 2021 should be recommended for rizatriptan so that patients who are stabilised on rizatriptan would not be disadvantaged. We believe that if one triptan is suitable for downsheduling then it would be appropriate for all of the triptans to be downscheduled at the same time in the absence of evidence that there is a particular reason why one particular triptan does not meet the scheduling criteria.

[2] https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-acmsaccs-meetings-march-2020