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Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration

Scheduling delegates' interim decisions and invitation for further comment:
ACCS/ACMS, November 2017

Melanotan II

We thank the ACMS and delegate for their consideration of the scheduling of melanotan II which raises a number of concerns relating to its current availability.

The NSW Poisons Information Centre notes in the Scheduling Policy Framework for Schedule 10:

The substance has a public health risk that substantially outweighs the benefit to the extent that no other Schedule would provide appropriate public access to any proposed or known products.

The ACMS notes in their 52E summary "Benefits: There is no body of evidence demonstrating therapeutic benefits of melanotan II." In addition, a number of risks to individuals through medication error, toxic effects and melanoma risk were described and public health risks included infection and false information around skin cancer protection with regards to sunless skin tanning. On balance, melanotan II meets the criteria for schedule 10 as there is an established public health risk and no benefits demonstrated. In addition, we would like to present new information on why schedule 4 is inappropriate for melanotan II and would not adequately provide appropriate public access in consideration of its public health risks.

There are a number of Australian websites at present which require online registration and a medical assessment to be completed by an online/phone-based doctor, then they will provide the script and have the product sent out via online order. Compounded products will avoid SAS approval requirements. Examples as follow:

<https://www.peptideclinics.com.au/store/vip/medical/index/>

Advertised as safe enhanced tanning requiring a 6 minute form to be completed for online doctor's approval.

https://mrcpeptides.com.au/buy_melanotan-ii_6_13.html

Provide full blood analysis and medical questionnaire before melanotan II can be ordered.

https://peptidedirect.com.au/?gclid=EAlaIqObChMIpeCmqgmk2QIViBSPCh3TugMgEAAYB_CAAEgLDUvD_BwE

Registration required and a member of their medical team will contact you.

<http://www.comocompounding.com.au/products-services/>

Online compounding pharmacy selling melanotan II.

Scheduling melanotan II to schedule 4 will have no impact on the sales through such websites. Furthermore, based on a recent case handled at the NSW Poisons Information Centre on 4 February 2018, discussion with a caller who administered a ten times overdose after purchase through a compounding pharmacy reveals the recent availability of Australian online stores and medical assessment are providing further false reassurance to users of the quality and safety of products. On 16 February 2018, another case involved a 21 year old female who had presented to a GP with signs of infection, five days after injecting melanotan which was a vial that had been in use for 3 months and stored outside of refrigeration. Poor injecting practices will continue with its continued availability through online pharmacies.

We trust the additional information provided will be of benefit in classifying melanotan II as having a public health risk that substantially outweighs its zero benefits and no other schedule can provide appropriate public access, i.e. Schedule 10.

Yours sincerely,

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