

FOI Request 1324 in relation to Sodium Oxybate or Xyrem

The request is for the following:

"I am seeking documentation that is the actual 'written advice' provided to UCB Australia by the TGA in regards to the aforementioned pre-submission discussions. I am not requesting any other correspondence related to or surrounding that written advice.

The 'written advice' refers to part of the correspondence between the TGA and UCB Australia related directly to pre-submission discussions about the drug Xyrem (Sodium Oxybate). These discussions took place in 2018 and written advice was provided by email from TGA to UCB Australia. I refer specifically to the two pre-submission discussions that are described on page 2 of, "Inquiry into Sleep Health Awareness in Australia - Submission 131 - Supplementary Submission 1," which is uploaded at:

https://www.aph.gov.au/Parliamentary_Bus...

"The TGA has been approached in 2018 by potential sponsors for sodium oxybate and has had two pre-submission discussions. Written advice to the sponsors was provided by the TGA at the time and no follow-up applications have been received to date."

I understand further that some of the documents relating to these discussions may be published journal articles or studies. If the documents contain information that is published elsewhere I am not seeking it to be reproduced in full, I am only seeking a citation or reference information so that it is identified..."

Schedule of Relevant Documents

Doc. No.	Author	Addressee	Date	Description	Pages	Decision	Relevant Sections of the FOI Act
1	TGA	UCB Australia Pty Ltd	14/06/2018	Email: Pre-submission meeting request	5	Release in full	s22
2	TGA	UCB Australia Pty Ltd	6/04/2018	Brief: Pre-submission meeting	25	Release in full	s22