



Lea McAuley  
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To: Graeme Harris/TGA/Health@Health\_gov\_au  
cc: Terry Lee/TGA/Health@Health\_gov\_au, Jeff Ibbotson/TGA/Health@Health\_gov\_au, Janice Larkin/TGA/Health@Health\_gov\_au  
Subject: Subsection 19(5) Authorisation

Graeme

I refer to our earlier conversation and advise, that rather than revoking the authorisation, the delegate of the Secretary who issued the authorisation, write to the doctor in the following terms.

"Dear

I refer to the authorisation given to you under section 19(5) of the *Therapeutic Goods Act 1989* ("the Act") to supply [SET OUT DETAILS].

By operation of subsection 19(6) of the Act, an authority under subsection 19(5) of the Act may only be given to a medical practitioner included in a class of medical practitioners prescribed by the regulations.

The authorisation given to you was given to you as a medical practitioner included in the class of medical practitioners prescribed under Regulations 12B(1)(a) of the Therapeutic Goods Regulations 1990 ie medical practitioners 'engaged in a clinical practice at a hospital and endorsed by the ethics committee of the hospital for the purposes of subsection 19(6) of the Act.

It has come to my attention that there is no ethics committee at [...] to endorse you as a medical practitioner for the purposes of subsection 19(6) of the Act.. This means that the authorisation given to you should not have been issued. Accordingly, you are no longer authorised to supply [SET OUT DETAILS]."

I have used the words "should not have been issued" rather than stating that the authorisation was of no effect in case questions arise about the legality of any supply made by the doctor before receipt of this notice.

I suggest that the hospital/ institution are advised simultaneously. The notice to the hospital should also refer to the relevant legislation.

I am happy to assist in drafting a letter if you wish.

Lea McAuley