

During the public hearing in Sydney on Tuesday 21 June 2016, I was asked a question by Commissioner Chester, which I took on notice.

Her question was in relation to data exclusivity and our submission that it must not be extended.

Specifically, she asked in relation to a situation in which data exclusivity were to be extended:

“Would Mylan replicate trials for biosimilars while data exclusivity is still in place?”

I have conferred with my colleagues and the answer is:

Unequivocally no, we would not replicate the full set of clinical trials to obtain the data tied up by data exclusivity. It would be commercially non-viable to repeat them and we would just wait for the data exclusivity period to end. This of course means delayed access for Australians to quality, safe, efficacious and affordable medicines. In the case of biologics and follow on biosimilars, the costs are extremely high and would deny many patients access to the most appropriate treatments. As you may be aware, the TGA will not begin its evaluation of a dossier until the data exclusivity period has expired.

Please feel free to contact me if you require any further information.

Kind regards

Robyn Ronai

Alphapharm Pty Ltd