15 September 2019

Regulatory Compliance Section
Regulatory Compliance and Education Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To whom it may concern,

I am writing to provide submissions on the draft *Therapeutic Goods (Declared Goods) Order 2019*. I am happy for this submission to be published on the TGA's website with my name (which is at the end of this letter) redacted.

I am an allied health professional and have worked with young people and adults with mental health issues for much of my career. My role is to assist them to participate in a satisfying and meaningful life and to support them to adopt strategies to best support their mental wellbeing. Many of the clients suffer from depression and anxiety and a constant battle is the immense impact the side effects of their medication have on them.

Many of the clients are closely monitored by medical professionals and are very compliant with taking their medications even though the side effects are only marginally better than enduring their mental illness symptoms. The main reason that they go off their medications and become unwell is because they can no longer tolerate the side effects. Some examples of these side effects include muscle spasms, pain, headache, nausea and numbness both mentally and physically. When people stop taking their medications suddenly they can become psychotic and or suicidal.

My understanding is that clinical trials have shown that taking Neurofolin in combination with the client's regular medication for anxiety and depression can have a very positive result. Some psychiatrists have found that they are able to reduce their patient's pharmaceutical medication by half and therefore their side effects by half. This is a marvelous result and does so much to help people have a stable and meaningful life and STAY on their medications.

The passing of the proposed declaration will cause the removal of Neurofolin from the Australian market and catastrophic damage to people with mental illness that have finally found a balance in their lives – a balance that until this product was available in Australia they were unable to establish. It would be grossly negligent for the TGA to discount this impact.

With the current Royal Commission into the care of Australian's with Mental Illness, and the well-recognised limitations of medications, the TGA should be assisting the community however possible to better manage mental health, which very reasonably includes the use of dietary management with FSMPs. The TGA should not be creating unnecessary hurdles and barriers to people accessing a safe and helpful product such as Neurofolin.

For the above reasons, I ask that you do not proceed with the making of the proposed declaration.

Yours sincerely,

[redacted]