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 and contact details (which are at the end of this letter) redacted.

I am a qualified **[REDACTED]** working in a pharmacy setting, providing both long consultations and brief short consultations. I recommend that patients use Neurofolin for depression, anxiety, obsessive compulsive disorders and other mental health conditions; often in conjunction with their prescription medication. I have been recommending Neurofolin since early 2018, with many patients reporting successful results while taking it. During that time, I have not observed any adverse safety issues or concerns, or any negative interactions with medications. Also, during the time I have recommended Neurofolin, I have not observed any cases of patients taking Neurofolin in lieu of seeking professional medical advice. I am aware that FSMPs are only for use under medical supervision and I always ensure that patients have sought medical advice with their primary practitioner or mental health practitioner before purchasing Neurofolin.

I believe that Neurofolin is used to address nutritional deficiencies that arise secondary to a primary disease or condition (in this case, folate disorders) including those with the MTFHR genetic mutation and those with a higher need for folate.

I believe that the removal of Neurofolin from the market would be detrimental because

- the evidence supports the role Neurofolin plays in addressing folate deficiency in those individuals with folate metabolism disorder;
- the evidence also supports the view that adequate serum folate levels are important for anti-depressants to achieve remission of depression symptoms and therefore the removal of the product is likely to increase the burden of depression on the health system due to poorer remission rates; and
- there are no identified or suspected health or safety concerns regarding Neurofolin.

The TGA notes in the consultation paper that the special access and authorised prescriber schemes are available as a way of maintaining access to Neurofolin in the event that a s 7 declaration is made. I believe that these schemes will deprive the majority of individuals who currently use Neurofolin from continued access to it because both schemes rely on time-poor treating practitioners to apply to TGA. Both processes are arduous in terms of the documentation required. As a **[REDACTED]**, my view is that neither the special access scheme nor the authorised prescriber scheme are realistic alternatives to reduce the detrimental effects of removal of Neurofolin from the market.

Yours faithfully

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[REDACTED]

[REDACTED]

[REDACTED]