17 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 have only just become aware that the Therapeutic Goods Administration is seeking comments from interested parties on the making of an order to declare goods containing folate substances, where these goods are represented as being food for special medical purposes, or being for dietary management of a disease, disorder or medical condition, to be therapeutic goods.

Given the unreasonably short timeframe, and lack of publicity, for the consultation, I will confine my comments to the implications on the FSMP Neurofolin.

It is my understanding that the TGA is not questioning the safety of Neurofolin and that it has been shown to assist considerably with the effectiveness of drugs prescribed for people suffering from depression who may have a folate deficiency. It is intended as a food supplement not as a therapeutic good. There is no evidence of which I am aware that it is a medicine in its own right for the management of depression. To declare it a therapeutic good would be grossly misleading. Furthermore I understand that products of the nature of Neurofolin are classified internationally as FSMP not as registered medicine as they are not intended as a medicine in their own right. The draft declaration certainly undermines the core intention of the classification of Food for Special Medical Purposes.

It is also my understanding that the TGA was approached regarding classification of Neorofolin as an SMPF before it was launched on the market but the TGA refused to provide any clarification or confirmation and directed Grunbiotics to utilize independent expert regulatory consultants. I understand that five detailed expert independent assessments were subsequently conducted and all have confirmed that it is correctly classified as an FSMP. This situation has been exacerbated by the fact that the TGA has not been willing to give any reasons as to why it now wants to classify Neurofolin as a therapeutic good. Nor are any reasons given in the explanatory memorandum from the TGA except that classification as a therapeutic good ensures that those goods are of appropriate quality, safety and efficacy. It is my understanding that none of these issues exist in relation to Neurofolin.

Despite being of modest means I invested $50,000 in the development of Neurofolin because of a number of people who I know (including some family members) who suffer from depression, and I am aware of the devastating impact this has on their lives. A number are using the product to complement their

prescription drugs and it has assisted them considerably. Consequently, their treating clinicians have recommended Neurofolin to other patients with considerable success.

In the event that Neurofolin is unable to be classified as FSMP it will almost certainly be withdrawn from the market. Because of patents it will be very difficult to replace with an as effective product. This will have a devastating impact on people (and their families) who now depend on it. It will also result in significant loss to a number of small investors such as me who were motivated by a desire to help those who suffer from depression but could ill afford it.

On a broader note, I hold that it is unreasonable for a Federal body to overrule State Law and intention by administrative fiat without the strongest and most transparent reason. Such action undermines legislative framework and creates instability and confusion for consumers and business. In this instance it also creates instability and confusion for healthcare professionals and patients and prevents access to safe and effective strategies. It also undermines business and investor confidence and product research and development.

In conclusion, I see nothing but harm without good reason emanating from the action proposed and urge that it not proceed.

Sincerely

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