GRÜNBIOTICS
Medical Nutrition. Improving Lives.

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Regulatory Compliance Section
Regulatory Compliance and Education Branch
Therapeutic Goods Administration
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Submission in response to "Consultation: Proposed clarification that goods are therapeutic goods - goods containing folate substances in certain circumstances.

Let me say from the outset that I am one of the founders of Grünbiotics. We make Neurofolin, a Food for Special Medical Purposes (FSMP) that contains L-methylfolate calcium – a bioavailable form of folate. As you would know, it is our production and sale of Neurofolin which originated this call for submissions. A Section 7 declaration would force immediate withdrawal of our product from the market and the loss of its availability to thousands of Australians who are currently using it for dietary management purposes in conjunction with their depression medication.

I would like to start by objecting to the term "clarification". This makes it sound like the market in general, and Grünbiotics in particular, may be confused regarding the classification of therapeutic goods and the classification of FSMPs. There is no confusion. We sought advice right from the start from Food Standards Australia and New Zealand (FSANZ), health authorities in two states, the TGA itself, and the best experts we could find, including those on the TGA website. This proposed "clarification" is a fundamental change to the original intention to Food Standard 2.9.5. which governs FSMPs.

What the TGAs consultation title really ought to say is "Consultation: Proposed change to the definition of FSMPs, and the re-classification of certain FSMPs as therapeutic goods."

Let me also add that to date, the TGA still has not provided any legal or scientific evidence to justify such a declaration. The TGA appears to have reached this conclusion internally, for reasons which are opaque and vague, and without substantiation. While this is acceptable in personal decisions, it is not acceptable for decisions that will affect many thousands of Australians through loss of access to products that are safe and helpful. Please provide substantiation for your decision.

Aside from limiting the range of health interventions for millions of Australians, this declaration will also have a substantial effect on the many people involved with our company in the development, production and sale of our products, and indeed the small mum and dad investors who have supported us in good faith to create FSMPs under the existing food standard 2.9.5 and existing definition of an FSMP.

And to what end? What is the purpose of this reclassification? Will it serve a public good? What public good will it serve? The product and folate is widely acknowledged as benign and safe. What harm, or benefit will arise from a narrower definition of FSMPs? Why the need to reclassify it now?

Clearly, I have a personal interest in this - but let's move beyond self-interest and look at the wider implications. Let me address this issue, both from the notion of the public good and my own personal response.

Public Good

You propose to use subsection 7(1) of Therapeutic Goods Act 1989 to declare FSMPs that contain folate as therapeutic goods. Why stop at folate? Why this particular substance? What about arginine? What makes folate different? What about the many other medical foods that are currently on the market?

You propose under subsection 7 (1) to declare all FSMPs that address issues arising from folate metabolic disorders as therapeutic goods. However, the definition of a Food for Special Medical Purposes is a food that is formulated for

people " … who have special medically determined nutrient requirements or whose capacity is **limited or impaired to** take, digest, absorb, **metabolise** or excrete ordinary food or certain nutrients in ordinary food; " (bold is mine). Your proposed redefinition flies in the very face of what an FSMP is meant to do.

It seems that your issue is definitional and wider than our product Neurofolin, or indeed products that contain folate. You should address the definition of an FSMP and not single out one single product, or class of products. Fairness is very important to Australians - indeed our current Prime Minister, Scott Morrison, kicked off his election campaign with "A fair go for people who have a go". Your proposed amendment is not fair, and certainly does not help Grünbiotics, who had the temerity to "have a go" at the global FSMP market.

Impact

There are two important sectors that will be affected by your proposed declaration:

1. People who have a need of FSMPs - and in this case, particularly those with folate disorders. They will no longer be able to easily or readily access a product supported by the most up-to-date scientific and clinical literature.
2. The many scientists, researchers and production staff, who will lose jobs and years of effort. This nascent industry is having its very foundation ripped from under it. Yet again Australia is prevented from competing on the world stage. Where will the next generation of jobs come from?

The health and well-being of people with chronic diseases should be first and foremost your concern. Yet despite that, you propose to take an action which will have deleterious effects and make suitable products harder to access for thousands of Australians with depression that have serious folate metabolic disorders that stop them adequately processing folate.

Improvements

You've asked for suggested improvements.

1. As far as the consultation is concerned, do not proceed with this declaration. The current regulation is adequate. If your real concern is public safety, then write to the food authorities in each state and ask that they ensure the product is made, promoted, and distributed in line with standard 2.9.5. This can be done more than adequately under the current legislation.
2. Genuinely work with Grünbiotics to make changes to the product that would allow it to stay on market as an FSMP.

There is a larger issue of the TGA's credibility and effectiveness. This consultation process has the appearance of being rushed and ad hoc. It erodes the public's trust and diminishes the great deal of good work undertaken by the TGA. Therefore:

1. Get the definition and regulations right the first time. Don't rely on blunt regulatory instruments to fix errors or "unforeseen" circumstances. Industry needs a stable and robust framework. This is how jobs are created.
2. Give adequate consideration to the wider economic landscape. At a time when Australia needs more than ever to become the "smart country", the "clever country", and to innovate, actions which destroy a burgeoning industry should be avoided. Your attempt to "clarify" only serves to discourage innovation.
3. Work more closely with the states and FSANZ. Perhaps there should be one national body much like the Food and Drug Administration (FDA) in the US. It is not Grünbiotics' fault if the original standard was poorly drafted, nor should we suffer as a result of that.
4. Do not use a single case or class of products to experiment with definitions. This is unfair to many honest and hard-working Australians trying to do their job.
5. Respond to requests for assistance and advice when originally sought - not when they become an issue.
6. Be truly consultative and collaborative. Sophisticated democracies such as Australia's required genuine collaboration. Dictating an outcome is shortsighted and likely counter-productive in the long-term.

Costs

The costs of the TGAs proposed "clarification" have been, and continue to be enormous.

This issue has been dragging on for over a year now. Grünbiotics have repeatedly requested a collaborative approach and asked for clarification - yet none has been forthcoming. It took nine months for the TGA to agree to a meeting. At that meeting, many of the participants from the TGA were not across the issues. After more than 12 months, the TGA had still not properly considered the scientific evidence provided. Why the delays? If this issue is important enough to make a declaration under subsection 7(1) then why was it not important enough to give it full attention from the beginning?

Why has it not been possible for the TGA to work with Grünbiotics to amend Neurofolin so it better meets the TGA's own expectations, and unique interpretation, of what an FSMP should be? Why has the TGA ignored the advice and legal opinion of the eight legal/regulatory consultants and departments provided by Grünbiotics? Many of these were provided at great cost to Grünbiotics and at the request of the TGA. They unanimously expressed the opinion that Neurofolin is an FSMP. Was it because the opinions provided were not what the TGA wanted to hear? Had they been opinions the TGA had wanted – perhaps they wouldn't have been ignored?

Many of these opinions were obtained from consultants accessed from the TGAs own website.

Cost

The most important cost is for the people suffering from a condition that would be helped by an FSMP, in our case folate deficiency in people with depression. I've covered this above. They are not the only costs.

Mum and Dad Investors will Lose

Many of our investors have given time and money to Grünbiotics to develop Neurofolin. Their investment was on the basis of advice received that our product is indeed an FSMP under standard 2.9.5. As outlined above, we did seek advice to this effect from the TGA, FSANZ, and state health bodies.

Personal

I have spent the peak of my professional career – the past eight years working at Grünbiotics to develop medical foods so that Australians can have access to more comprehensive health care. For many of these years I worked unpaid, forgoing income from other sources.

If this proposal goes ahead, we will need to withdraw Neurofolin from the market. I will have lost the best working years of my career, through no fault of my own. These are years at my peak, and are not recoverable as I move towards retirement. Personally there is a huge time and opportunity cost.

In addition, there is a financial cost. On current projections I stand to lose millions of dollars. Again, this is unrecoverable.

To summarise:

- There is a cost to the Australian public - poorer health outcomes.
- There is a cost to Australian industry, and thus jobs - uncertainty and a disincentive to innovate.
- There is a cost to me personally - eight years of the peak of my professional career, and potentially millions of dollars.
- There is a cost to the TGA - the appearance of poor decision-making, ad hoc and reactive actions, a loss of trust and integrity.

I submit that you withdraw your proposal. If changes need to be made, then make them properly, and thoroughly at the definitional level and allow time for companies to transition, so there is no disruption in the market.

Sincerely

Cris Popp

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