

Sarah Galbraith
[REDACTED]

11 March 2019

RE: Consultation on Options for the regulation of Faecal Microbiota Transplantation materials

Thank you for receiving public comments on the topic of the options for regulation of Faecal Microbiota Transplant materials (FMT). I am writing as a concerned member of the public, who has a personal and familial interest in seeing FMT continuing to be made publicly available under the guidance of a qualified medical practitioner.

I am a person who has always taken proactive interest and action with respect to my health. Through focus on exercise, diet, stress management, sleep and both pharmaceutical and complementary nutritional supplementation (all managed under medical supervision), I have been able to maintain a level of positive general health. And yet despite these proactive measures, I still suffer health conditions which require a strong and healthy immune system, such chronic sinusitis, gastro-oesophageal reflux disease, hyperinsulinemia and hypothyroidism, to be kept under control without additional intervention or suffering.

In my family, I have a father with Parkinson's Disease, a stepmother with Alzheimer's Disease, and have lost both my mother and a younger brother to cancer.

All of these conditions are the subject of recent and ongoing research about not only the impact of a healthy immune system, but also the potential benefits of FMT as a preventative or prophylactic treatment.

Any classification of FMT that could limit the ability of sensible people to proactively explore FMT's benefits under the guidance of a registered medical practitioner seems like a retrograde step for the Australian health system, and its ability to both support the general level of health of its population, and its ability to innovate to find new solutions.

I feel it's worth noting that FMT could be considered to be a threat to a strong and wealthy pharmaceutical sector, given it is a treatment that seeks to decrease reliance on a category of strong profit for this sector, antibiotics. As a taxpayer, I would hope that the TGA would seek to balance the interests of Australian individuals and the taxpayers who contribute to enable a high level of medical care when issues arise, with those of wealthy corporations.

The most logical classification for FMT would be one which allows its use to be managed through qualified medical practitioners in appropriate and affordable clinical settings, with appropriate oversight to the gathering, storage and application of the FMT materials. A classification that limits the affordability and accessibility of its potential use (outside of approved use for rCDI) to clinical trials could be devastating to progress in an emerging and promising field of innovation in Australia.

The approaches taken by the European Union and UK appear logical and aligned to the outcomes above.

Thank you for considering my submission.

Sarah Galbraith