Health
Sydney
Local Health District

Professor Rupert WL Leong
MBBS, FRACP, MD, AGAF
Senior Staff Specialist Gastroenterologist
Conjoint Associate Professor of Medicine, UNSW
Director of Endoscopy, Concord Hospital, Sydney

Therapeutic Gastroscopy & Colonoscopy
Endoscopic Ultrasound
Confocal Endomicroscopy
Inflammatory Bowel Diseases

Concord Hospital
Ambulatory Care Endoscopy Unit
Level 1 West, Hospital Rd
Concord NSW 2139
Tel: 9767 6111
Fax: 9767 6767
Provider No. 205675AJ

Department of Health
Therapeutic Goods Administration

20 Feb 2019

Re: Consultation – options for the Regulation of Faecal Microbiota Transplantation materials

Thank you for the opportunity to comment on the proposal to regulate faecal microbiota transplantation (FMT) in Australia. This is an important initiative designed to harmonize and optimise safety and efficacy of a new treatment paradigm already proven to benefit patients with life-threatening *Clostridium difficile* infection, a life-threatening condition associated with the use of antibiotics, immunosuppression and in the elderly. More recently, several clinical studies demonstrated the efficacy and safety of FMT on the treatment of ulcerative colitis. These early studies demonstrate that modifying the faecal microbiome may induce therapeutic benefits on gut diseases. These are at times otherwise incurable conditions. Importantly, Australia is one of the leaders in this field. We have provided the best clinical trials results published in the top journals *The Lancet* and *Journal of the American Medical Association*.

Research in this field is only beginning. Research would not be possible if there were regulatory restrictions that make it difficult to perform FMT. Our Clinical Microbiology colleagues have indicated that they would not be able to prepare for- or perform emergency FMT if they were regulated through GMP conditions. At the same time there needs to be accepted standards and written protocols and recipients need to accept the risks and benefits of treatment. Clinicians and researchers need to abide by ethical principles and FMT needs to be conducted in the right clinical settings.

FMT is not a drug. They are produced by defaecation of a screened donor, and provided through enemas by the recipient. Screening processes are required to ensure that the donor does not harbour infectious agents or have any ill-health that might be transmissible. However, FMT has been conducted at home by consenting adults for many years. Over-regulation would not change this or might increase home-FMT further.

Given the complexity of FMT, we formed a multidisciplinary steering committee that I chair that aims to discuss and recommend donor selection and screening, indications, development of FMT centres and future research. Members include Dr Sudarshan Paramsothy, Dr David Andresen, Dr Viraj Kariyawasam and Dr Craig Haifer. We have decided on a working timetable, criteria for panel nominees, and proceeded to nominate panel members. We have sought endorsement from the Gastroenterological Society of Australia, Australian Society of Infectious Diseases and The Royal College of Pathologists of Australia and have representatives from each of these organisations. Panel nominees include gastroenterologists, infectious diseases specialists and pathologists from across Australia and overseas. We have invited the TGA to participate and will involve a consumer/ patient representative.

We will employ a modified Delphi technique, an accepted method of developing consensus based on an unbiased systematic review of the published literature. There will be 2 rounds of online voting on statements and one face-to-face anonymous voting round with discussion to be held in Sydney Australia on

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Saturday 29th June 2019. We will incorporate the Level of Evidence and Recommendation Grade as per NHMRC Guidelines recommendation on each statement. Where relevant a PICO approach will be used.

Outputs of this body of work will be published in a peer-reviewed journal and presented for comments at national conferences. We hope to generate material the TGA can use in the development of an acceptable regulatory approach that reflects the views of clinicians, researchers and consumers/ patients. We wish to invite a representative from the TGA as a member of this consensus group.

The proposed timetable for work is as follows:

Activity	**Proposed completion date**
Assembly of steering committee and preliminary literature search Teleconference with steering committee in order to discuss criteria for panel members, identify important questions needing to be addressed and to refine draft statements	August to November 2018
Invitations sent to potential panel members	December 2018
Draft statements completed by steering committee	December 2018
Draft statements sent to panel members and first round of voting opens	2nd January
First round of voting closes	31st January 2018
Results from first round of voting, de-identified individual opinions and literature summary made available to entire panel	15th January 2019
Statements refined	February 2019
Second round of voting (online)	March 2019
Statements refined	April to May 2019
Third round of voting (face-to-face)	Saturday 29th June 2019
Consensus statement drafted, sent to panel members for signing	June/July 2019
Publication written and sent to GESA, ASID and College of Pathologists for endorsement	August-September 2019

Yours sincerely,

Professor Rupert Leong MBBS, FRACP, MD, AGAF
Chair, FMT Consensus Group