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Department of Health
Therapeutic Goods Administration

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

Response of the Australian Consensus Working Group response to the TGA's draft standards for Faecal Microbiota Transplantation (FMT) products.

The Australian Consensus Working group recognises the need for regulation of FMT products to achieve the shared goals of providing safe, efficacious and widely available FMT therapy in Australia. The group broadly supports the TGA's draft guidelines, noting that donor screening recommendations in the draft document align well with the recommendations from the Consensus group that have been accepted for publication in the peer-reviewed journal *Gut*.

Members of the consensus group, however, are concerned about the requirements that some FMT products meet class IV IVD test validation standards. This important issue was discussed at lengths during the working group process and it was felt that the lack of availability of validated assays for FMT donation was the key driver in not achieving consensus on the recommendations for the types of assays. Although the consensus working group acknowledges that further validation of tests used in donor screening would be ideal, there are concerns that such validation is not practically achievable. Imposing a regulatory requirement to use tests that currently do not exist is problematic, although there is agreement that where validated assays are currently available, that regulation should mandate their use. There are concerns from the consensus group that if these requirements are

imposed that this would encourage less donor screening and limit the ability to expand screening practices in response to changes in infection or resistance epidemiology. There are also concerns that additional costs involved in test validation could negatively impact stool banks and would encourage more production of FMT in less well-regulated or commercial settings. To acknowledge this limitation, the working group felt that donors, FMT recipients and practitioners should be informed of the limitation of donor screening using tests not validated for this purpose during the treatment process and informed consent provided with the understanding that the benefits of FMT outweigh the risks. A process to inform the TGA of the donor/ FMT product screening tests could be an appropriate regulatory alternative to mandating that all tests used achieve class IV IVD standards of validation.

The accepted manuscript of the Consensus Working Group recommendations awaiting publication in the peer-reviewed journal *Gut* is available upon request.

Yours sincerely,

Professor Rupert Leong MBBS, FRACP, MD, AGAF
Chair, on behalf of the FMT Consensus Working Group