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ASIA EDITION

Australia announces world first regulatory approval for donor derived microbiome drug

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BiomeBank to scale up its Good Manufacturing Practice manufacturing facility to meet increasing global demandfor its donor derived microbiome drug product

Australian startup BiomeBank has announced the first regulatory approval for a donor derived microbiome drug product worldwide.

The Therapeutic Goods Administration (TGA) has approved BiomeBank's product for restoration of gut microbiota in the treatment of recurrent *Clostridioides difficile* infection (*C.difficile*). *C.difficile* infection is the most common cause of health care associated diarrhoea, a debilitating condition with significant global unmet medical need.

The microbiome-based product will first be launched as a frozen syringe formulation for colonic and enema delivery with oral delivery capsules for improved patient access to be made available in the near future.

The startup intends to scale manufacturing of the donor derived microbiome drug product to meet the immediate medical need. In addition, the company will be progressing with the development of its cultured microbiome based therapies with the aim of alleviating microbiome mediated disease on a much larger scale.