

Regulation of microbiota: Tissue, drug or what?

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Presentation

Gut Microbiota

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The speaker reviewed the new European Union regulation classifying faecal microbiota transplantation as a substance of human origin (transplantation product), effective July 2024 with two-year implementation period, contrasting Europe's approach with the US commercialisation model.

KEY POINTS

- FMT is an established, guideline-recommended treatment for *Clostridium difficile* infection, effective in both recurrent and first-episode cases where the speaker stated it is much more effective than antibiotics.
- A 2024 European survey reported more than 2000 FMT procedures performed, with centres maintaining donor registries and screening protocols, though only about one-third reported serious adverse events to national authorities.
- The new EU regulation includes intestinal microbiota under blood, tissue and cell legislation, requires biovigilance protocols and physician involvement in donor screening, and mandates registries for long-term safety monitoring.
- The regulation references EDQM technical guidance and defines minimally processed FMT (sieving, centrifugation, cryoprotectants, lyophilisation, packaging) as a transplantation product, while substantially processed standardised products may become medicinal products.
- The speaker contrasted Europe's approach with the US, where commercial product approval led to closure of the non-profit Openbiome stool bank, resulting in more expensive products and no FDA-mandated registry.
- Implementation will be more difficult and expensive for centres, with the speaker estimating costs of at least 1500 to 2000 euros per preparation, though reimbursement remains unresolved in many European countries.

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