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Summary

Regulating the microbiome: Drug or tissue?

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Gut Microbiota | Mechanisms & Personalised Medicine

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The presentation reviews the evolving European regulatory framework for faecal microbiota transplantation, distinguishing between intestinal microbiota as a donated substance of human origin and industrially processed medicinal products.

KEY POINTS

- A 2020 survey indicated that less than 10% of European patients with recurrent C. difficile infection who meet the indication for FMT actually receive the treatment, despite the speaker stating it has a 90% cure rate and grade one evidence for efficacy.
- Since 2020, intestinal microbiota is firmly regulated as tissue in Europe under the new substances of human origin regulation, which came into action and gives countries three years to implement it fully.
- The regulation now covers breast milk and intestinal microbiota as substances of human origin and requires unpaid voluntary donation, national regulatory oversight, donor screening standards, and mandatory outcome registration.
- The speaker stated that FMT is now established in most European countries and is used in routine clinical care, with potential future use in clinical trials for PD-1 inhibitor response, GVHD, recurrent UTIs, and ulcerative colitis.
- No substances of human origin-derived medicinal products are yet clearly marketed in Europe, though the European Commission is ready to discuss with scientific communities and industry about where to place new products derived from donor faeces.

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