


MICROBIOME THERAPEUTICS: ADVANCES & MARKET CHALLENGES

Probiotic May Represent Bone-Boosting Therapy for Osteoporosis

November 14, 2018  0

Research by the Emory University on the potency of the gut microbiome in regulating bone.

Published in *Immunity*, 13 November 2018

The briefing

The human microbiome: why our microbes could be key to our health

The Guardian, 26 May 2018

Article explains why the gut microbiome has become **hot research topic**:

It has been linked to:

- a number of diseases and conditions, from diabetes to autism and anxiety to obesity;
- how individuals respond to certain drugs.

Agenda

Depending on how microbiome therapeutics are positioned, different rules will apply to market access and advertising of those products.

- Legal framework food products, pharmaceuticals and medical devices
- Applicable rules to market access & advertising
- How about IP?

Legal framework pharmaceuticals

Medicinal product (art. 1.2 Directive EU/2001/83) is any substance:

- presented as having properties for **treating / preventing disease**
“medicinal product by presentation”
- which may be used in humans to restore, modify or **correct physiological functions** by exerting a pharmacological / immunological or metabolic action or to making a medical diagnosis.
“medicinal product by function”

Legal framework food products

Food (art. 2 Regulation 178/2002):

any substance or product, whether or not processed, intended to be ingested by humans.

Sub-categories include:

- **Food supplements:** concentrated sources of nutrients supplementing regular diet, marketed in dose form (e.g. pills or powders).
- **Medical foods:** used under medical supervision by patients, who's nutritional needs cannot be allocated by a modification of the diet alone.

Legal framework medical devices

Medical devices (art. 2.1 Regulation 2017/547)

- Any instrument, apparatus, appliance etc.
- intended by the manufacturer to be used for **specific medical purpose**
- such as the diagnosis / monitoring / prevention of a disease
- which does **not** achieve its **principal intended action** by a **pharmacological, immunological or metabolic means**.

NB According to ECJ C-109/12 (**Lyocentre**), classification of a product as medical device may differ from one Member State to the other.

Market access microbiome therapeutics

For each type of product, specific rules for market access apply

- Food products: *in principle* no prior market authorization required.
- Medicinal products: prior market authorization mandatory.
- Medical devices: CE-mark mandatory + notified body evaluation depending on risk profile.

Advertising microbiome therapeutics

Functional foods

- Use of authorized nutrition & health claims is permitted.
- Use of medical claims is strictly prohibited.

Pharmaceuticals

- Public advertising prohibited for prescription drugs.

Medical devices

- Advertising permitted only for compliant meddevs.

In cases of doubt: medicinal product legislation prevails.

How about IP?

Microbiome therapeutics marketed as a **food product / meddev**:

- most likely trademarks / trade names;
- potentially patent protection for meddevs, rarely for food products.

Microbiome therapeutics marketed as **medicinal products**:

- Patent protection mandatory to ensure return on investment for development. NB also consider **combination products**!

For **all types of products**:

- Potentially trade secret protection, provided that reverse engineering is not feasible.

This paves the way for ...

Michel de Baar – MSD

- Presenting Merck's microbiome early stage discovery center in Cambridge, MA.

Luc Sterkman – Caelus Health

- Presenting Caelus Health' targeted solutions for reduction of insulin resistance and prevention of T2DM.

Marco van Es - Winclove Probiotics

- Presenting Winclove's strategy for marketing probiotics.