

Cultivate Key Regulatory Intelligence & Best-Practices

- ❖ **Regulatory & Scientific** Expertise for the Microbiome - Health Industry (in Europe) –
 - *Regulatory intelligence & fore-sighting*
 - *Standards & regulatory texts*
 - *Scientific advice, best-practices, quality-by-design development*
- ❖ Scientific & Technical **Task Groups** Creation & Coordination
- ❖ **Day-to-day support** in the pharmaceutical development of Members' projects
(briefing packages/gap analysis, scientific advice, pharmaceutical standards)

*Membership benefits and supporting actions are crafted
to address the Regulatory & Scientific challenges facing the field*

Ensure Market Access for Microbiome-based Therapies

- ❖ Our mission is to **identify** and **confirm** the Regulatory and Scientific requirements for the development of microbiome-based medicinal products for the European Market.
- ❖ Once gathered, this knowledge is made available to stakeholders in order to support and de-risk pharmaceutical development – for the ultimate benefit of patients, many of whom suffer from high unmet medical needs.

We achieve this by applying a unique and innovative collaborative approach – ‘Share & Learn’

MMPS – A Full Spectrum of Medicinal Products

Donor
Influence



Product
Characterization
& Control



FMT (pharmacy exemption)

Fecal material-derived

Complex fermentations



Live Biotherapeutic Products



Non-living BPs



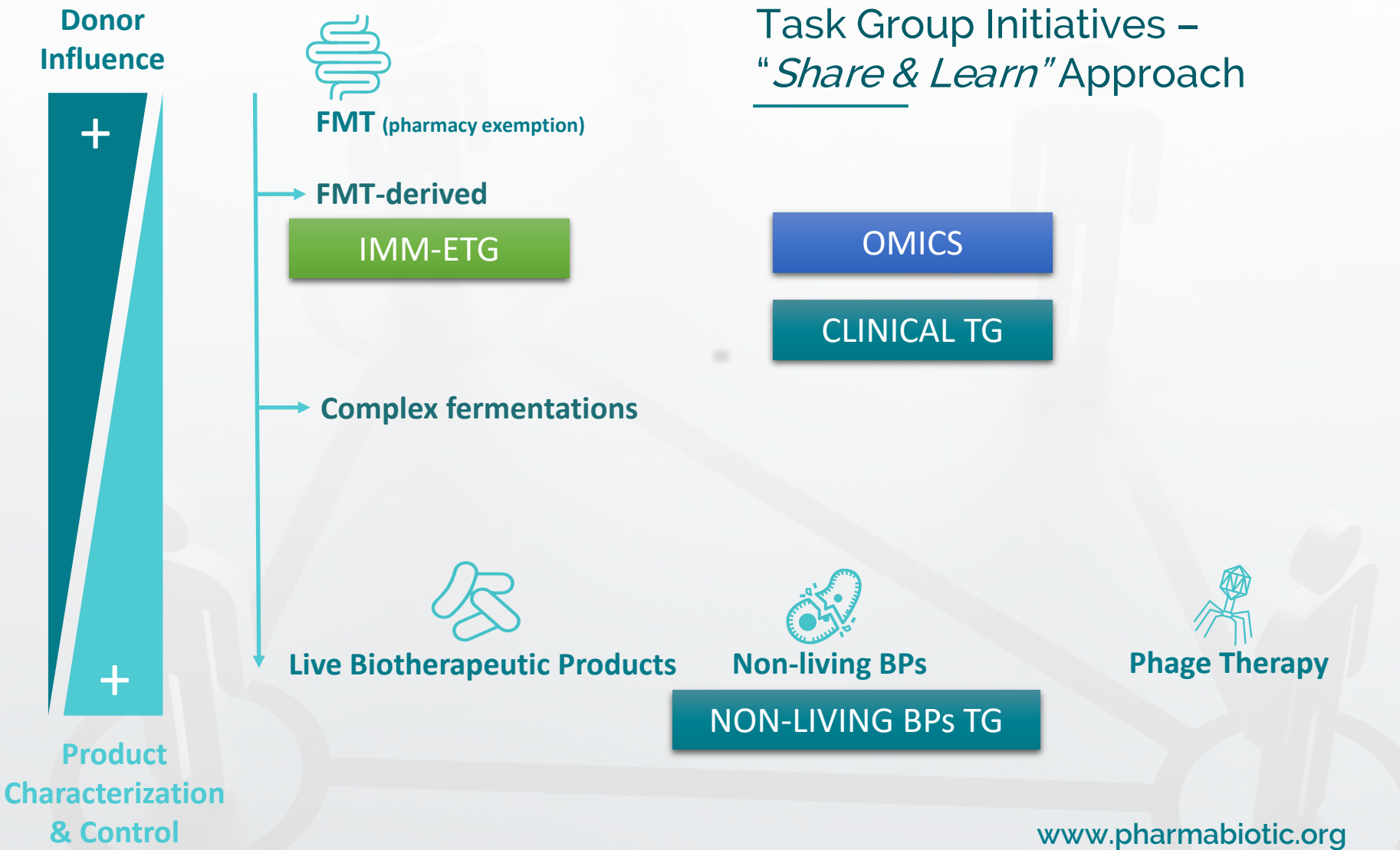
Phage Therapy

Each innovation has its own set
of Regulatory challenges

Regulatory status of a product is defined by its Intended Use, in a Target Population

*Prevent or treat human disease(s);
Restore, correct or modify
physiological functions*

MMPS – A Full Spectrum of Medicinal Products



The Overview Effect

Individual Challenges



**Member support for
interaction with authorities**

*Learning experience for the specific product
development*

**Identification of common
challenges and authorities' mindset**

*Learning experience for all members on
general topics*

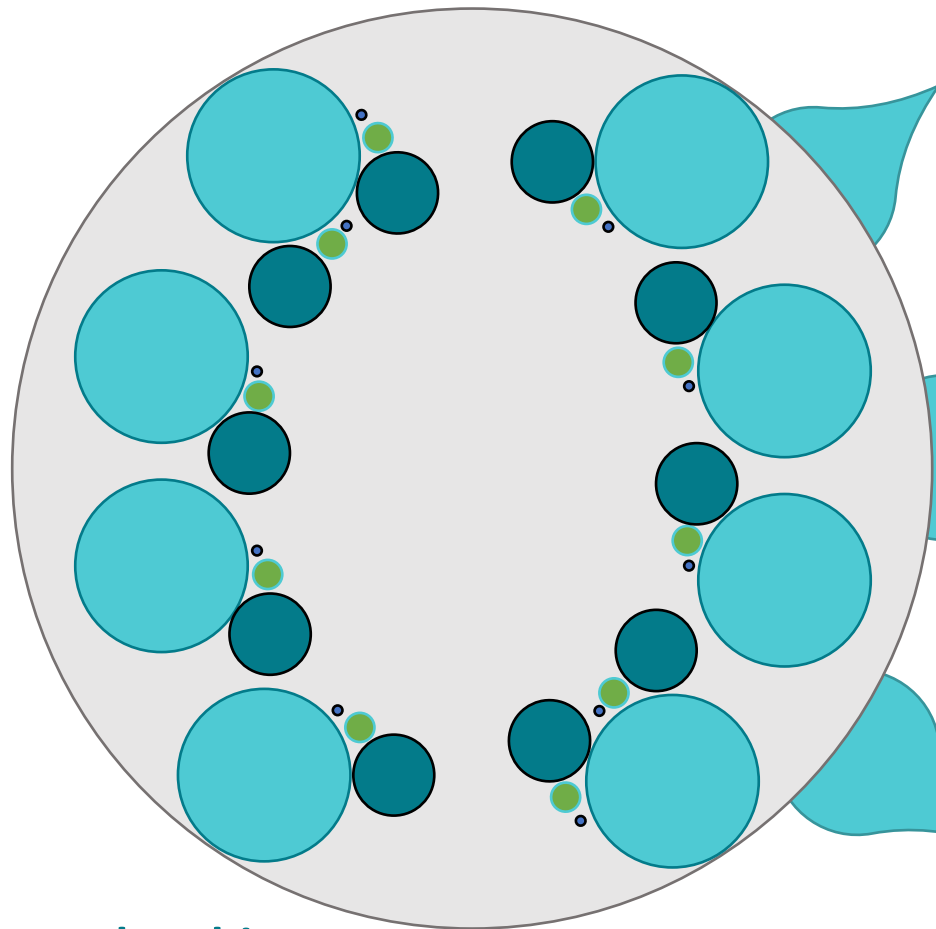
**Each member benefits from
their own experience**

*All members benefit from each others'
experience*

**PRI & Stakeholders
work in a mutually-
beneficial way**

The Overview Effect

Greater Insight



**Extensive collaborative
regulatory knowledge
available to Regulatory Members**

**Capacity & Legitimacy
to represent the
industry (*Eur Ph*)**

**Creates a 'category-
wide' awareness for the
benefit of each Member**

PRi Membership

Regulatory Membership 'Biotech' & 'Commercial' Levels

- ❖ Regulatory Update workshop for Member's Development team – GAP Analysis, Briefing Package drafting/support, targeted regulatory research initiatives, scientific advice support
- ❖ Year-round regulatory intelligence support by the PRI Staff; Regulatory Fore sighting, regulatory discussion and information regarding specific questions which are raised along the development steps, all questions and information relating to the regulatory needs of the Member's programme(s) - Yearly regulatory update at the PRI General Assembly (1/2-day session dedicated to Regulatory & TTO Members)
- ❖ Participation in/access to all PRI Task Groups (*'Share and Learn' sessions*)
- ❖ Access to the PRI network and support for introduction to service providers/partners/key ecosystem stakeholders
- ❖ Annual Member Fee: 'Biotechs' - €6K / 'Commercial' - €10K
(inclusive and scalable membership package)

Partnering Membership

Networking, Visibility & Task Groups

- ❖ Active visibility and promotion within a qualified ecosystem of microbiome-based medicinal product developers
 - LinkedIn / Email promotion of Partnering initiatives available to all PRI Members
 - Company logo / link to company website on [PRI Website](#)
 - Year-round networking support for potential collaboration connections (*“Partnering Platform”*)
 - Discounted attendance/preference for sponsorship at annual Pharmabiotics Conference & Partnering Event (www.pharmabioticsevent.com)

- ❖ Participation in/access to PRI Task Groups (*‘Share and Learn’ sessions*)

- ❖ Annual dedicated networking session for PRI Members

- ❖ Annual Membership Fee €1500 (inclusive and scalable membership package)