A Framework for Market Access Preparedness for microbiome-targeting therapies

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Background

Focus on regulatory approvals is no longer sufficient to guarantee product launch and commercial success of medicinal products. In addition, **product development needs to consider commercial risks following approval** and must integrate the payer, prescriber and patient point of view on value, and their evidence needs. Especially radically new treatment approaches such as microbiome therapies (MBT) **require carefully balanced strategies to achieve optimum price, market access and usage penetration.** In order to facilitate such strategy considerations and access preparedness, the commercial and access environment need to be more clearly characterised.

Objectives

To identify and structure key **factors determining commercial success of MBT** in order to create a systematic framework that enables **coherent evaluation, structured strategy development and evidence generation** planning to meet payer, clinician and patient expectations in an environment with few commercialised benchmarks.

Methodology

A pragmatic review of the MBT pipelines and market analyses was conducted considering sources such as clinicaltrials.gov, GlobalData[1], and information shared at industry conferences to identify the most prominent treatment approaches and indications. This facilitated the description of 'typical products' in order to create a common understanding of their characteristics and related access topics and challenges.

Based on existing general **market access planning frameworks** such as the Market Access & Pricing Chain and the Access Journey[2], key domains and factors that drive market access and pricing were outlined.

These frameworks describe how to incorporate the impact of payers, medical communities, providers, prescribers and patients in a systematic way to help make decisions for development and commercialisation.

These factors were then mapped against the previously identified product types to determine the set of main considerations for MBT technologies.

Results

Identified leading microbiome therapeutic areas and therapy types

Therapeutic area	Product type
Gastrointestinal Infectious disease Oncology Immunology	Faecal matter transplant (FMT) Live Biotherapeutic Product (LBP) Peptide & small molecule therapeutics

The Framework

The resulting framework was established around **three interconnected domains**:

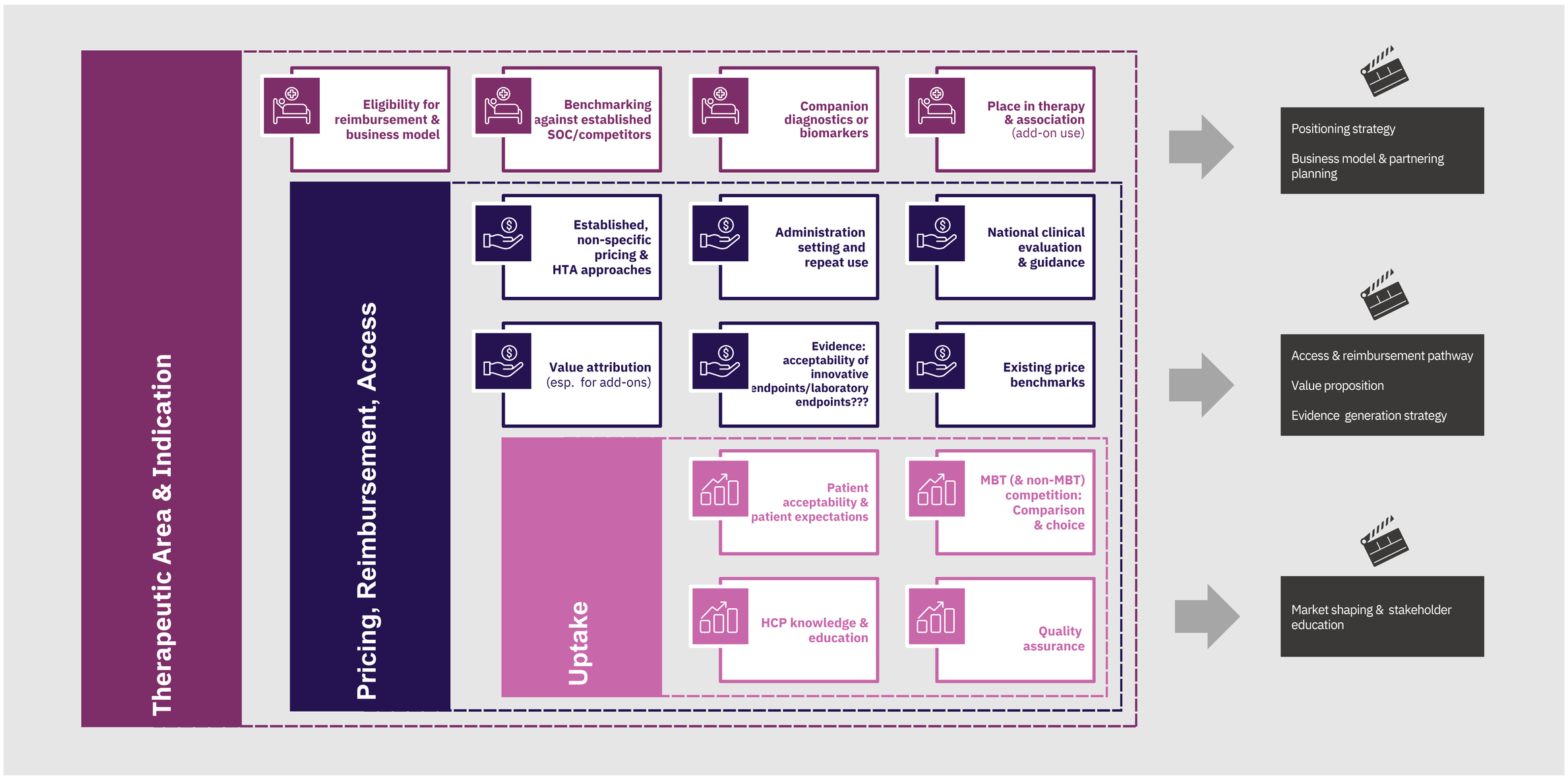
1. Therapeutic area,
2. Pricing, Reimbursement & Access policies,
3. Uptake.

With the product types in mind, **within each domain, four to six special topics** for MBT were identified that reflect the unique challenges for these technologies (see Figure 1).
Following on, for each domain, a specific **area of action for preparedness**, evidence generation or strategy development could be defined to inform access preparation activities throughout development and launch.

Access drivers link together with a background of business model and therapeutic positioning in the indication. Key factors further include value attribution and value demonstration vs. standard of care (SOC) and/or within encompassing treatment regimens. Ultimately, access needs to be assured through well-informed prescribing decisions and appropriate patient expectations for MBT.

Beyond the systematic structuring, the framework shows **domain interactions and a particular tension** between the domains 'Pricing, Reimbursement & Access Policies' and 'Uptake'; i.e. between the lack of MBT-specific value frameworks or dedicated reimbursement regulation on the one hand, and the lack of knowledge of the novel MBT field and necessary market shaping on the other hand.

Figure 1: MBT Market Access Preparedness Framework (MAPF)



Conclusion

A guiding framework was developed that describes key access driver and areas of attention for the emerging MBT field. The framework can provide a checklist and concept for access preparedness and evidence generation by structuring individual impact factors and putting them into context with each other.

Beyond facilitating a systematic overview of access drivers, the framework allows to understand the dynamics of the MBT access environments in the context of established products and reimbursement regulations, and the novelty of the microbiome field: MBT access topics combine various challenges encountered by other disruptive medical technologies, therefore requiring commercial strategies that combine 'the old with the new' and help navigate unbeaten tracks. These additional insights add value through a conceptualisation that is not set up in a linear way or as a checklist, but depicts the complex decisions and parameters as a network.

A next step could be to integrate the framework with a more complete Market Access Roadmap and to obtain feedback from different stakeholders involved in MBT development and use.

Find the poster here

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Abbreviations:

HCP: Healthcare professional; HTA: Health Technology Assessment;
MBT: Microbiome therapies; SOC: Standard of care

Notes & References:

1. some subscription content
2. Schoonveld, E. (2020). The Price of Global Health: Drug Pricing Strategies to Balance Patient Access and the Funding of Innovation (3rd ed.). Routledge. https://doi.org/10.4324/9780429320712