Contents

Figures

Tables

1

Driving Successful Commercial Product Launches

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Introduction

In 2025, the global medical device market was valued at roughly $570 billion and estimated to reach $1 trillion by 2034.[1] According to AdvaMed, at 40%, the United States (US) holds the largest percentage of the global medical device market.[2] Companies can no longer rely solely on regulatory market authorization for their products to be competitive, as their commercial success requires pricing, reimbursement, and market adoption.

However, these elements become challenging as the healthcare delivery model continues to transform owing to continued uncontrollable cost increases, higher healthcare utilization, and increased regulatory scrutiny. Purchasing decisions have been transferred from clinical decision-makers to economic buyers. Payment models have reassigned financial risk from payers (e.g., Fee-for-Service [FSS]) to providers (e.g., Value-Based Care). Therefore, healthcare providers are focused more than ever on controlling costs, being more efficient, and delivering improved patient care.

As these foundational shifts in the healthcare system continue, medical device companies must step out of their traditional role and evolve, focusing on solutions that reduce the cost of care, increase efficiencies, and improve patient outcomes by leveraging data and building intelligence into their products as essential parts of the new device value proposition to the multiple stakeholders within the healthcare delivery system.[3] A stakeholder's willingness to pay for a medical device will be tied to its impact on patient outcomes, cost-effectiveness, and support for quality-based performance metrics.

Companies, more than ever, need to understand the fluctuating landscape for successful commercial device launches. This chapter provides readers, especially those responsible for developing and building a regulatory strategy, with a framework to achieve a successful commercial product launch. Regulatory leaders and leaders from other cross-functional departments must recognize that their strategies and tactics should not be viewed from their perspective alone. Instead, they must understand that they are part of a process that has a patient-centered and market adoption end in mind. To thrive in this transforming healthcare environment, a collaborative cross-functional market access approach must be embraced by everyone in the organization. While a considerable portion of this Chapter discusses the US reimbursement landscape since it is the most complex, the European Union (EU) and other global markets are considered.

Commercialization Through Cross-Functional Collaboration With Market Access Mindset

In the past, when it came to Product Development Plans (PDPs), most medical device manufacturers either rarely considered payment, value, or their end users or only considered some of these factors during product launch. However, in recent years, medical