

# Regulation and reimbursement in the US healthcare sector

By Dan Edwards

Any company developing new products for the US medical market is well aware that a primary task is to define a regulatory approval pathway and reimbursement strategy. Major players in the healthcare field devote considerable resources to negotiating this complex and challenging system. However smaller or start-up companies often underestimate the level of expertise required, or fail to appreciate the full implications of a particular innovation strategy, especially for income generation.

In the US, new medical devices have to gain mandates both from the Food and Drug Administration (FDA), and from the CMS (Centers for Medicare and Medicaid Services) – the US Federal Agency which oversees Medicare (65+) and therefore approves the reimbursement of a good fraction of healthcare costs.

The FDA, with a remit to safeguard the nation's health, is understandably cautious when considering new products that claim innovation. For new devices, it demands substantial evidence to prove safety and effectiveness.

The two most used pathways for FDA approval of devices are the 510(k) route, for devices that can show 'substantial equivalence' to previously approved 'predicate' devices, and the PMA route, where long term clinical data is required. PMA can take much longer (potentially years longer) than 510(k). Consequently manufacturers have to decide at the outset whether to innovate incrementally, and generate moderate income faster, or to go for a breakthrough product with a greater investment of time and resources, but with the potential to generate significant income, only much further down the line.

Predicted income is further impacted by the CMS. If the mantra of the FDA is 'safety and effectiveness', the mantra of the CMS is 'reasonable and necessary'. The CMS wants to see both clinical effectiveness and value for money. It grants approval in the form of a code which caps the reimbursement given to the healthcare provider for a procedure. The device is allocated a proportion of the reimbursement and the provider can choose from a number of devices offering the same benefits. CMS codes are typically the same as those for equipment already in use, which also caps potential income for the new device.

An effective reimbursement and regulation strategy is therefore an essential part of a business strategy for healthcare players. Major companies can afford to support the development of PMA products, perhaps with a steady flow of 510(k) devices to underpin income streams. Smaller organisations, with more limited resources, need to determine their commitment from the outset, especially if they know they can deliver truly breakthrough technology. Expertise is required, not only to manage the detail of the approval process, but also to develop the longer term business plan – the 40,000ft

strategy – and to identify smart strategies which could accelerate progress. For example, in rare cases it may be possible to persuade the CMS to recode a procedure or the device within that procedure, which, although substantially equivalent to existing technologies from a regulatory perspective, delivers such significantly greater clinical benefits that comparison is irrelevant. Local, State-level approval is another route to consider, especially by companies already working in partnership with State-owned or funded organisations such as medical institutions.

Although many medical device developers want to revolutionise healthcare provision they need to appreciate the seriously lengthy timelines and investment involved, which can eventually sap the strength of even the most ambitious innovation team. By establishing a realistic strategy right from the outset, both incremental and breakthrough innovation can be planned for successfully, and healthy income streams maintained in the short and longer term.

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