



Global Trends in Reimbursement of Medical Technology

By

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EXECUTIVE SUMMARY

Reimbursement mechanisms for medical technology are highly complex in most countries, with different systems applicable to private and public healthcare, to different product categories and even to different regions of the same country. Not only that, but the goal posts keep moving, as countries reform and restructure their healthcare provision. Often reimbursement is used politically as a means of price curbing and slowing access to the latest technology, which leads to frequent overhauls of the systems in an attempt at achieving the best value for money.

These factors mean that for a medical technology company to be successful, it must devote significant time and resources to keeping abreast of the latest developments and devising strategies to best address the requirements.

Clinica's *Global Trends in Reimbursement of Medical Technology* allows the reader to analyse the role of clinical and economic data in obtaining reimbursement. The reader will also learn about the importance of technology assessment, which will maximise the chances of overcoming reimbursement hurdles and how to prepare a successful market entry strategy.

This report is a complete update of Clinica's best-selling 2004 report, *Gaining Reimbursement for Medical Devices and Diagnostics*, and features the latest information on requirements for reimbursement in the major markets. The report provides in-depth country profiles for the US, Japan, China, Germany, France, the UK, Italy and Spain.

Chapter 1 profiles the US reimbursement environment, paying particular attention to the highly fragmented, decentralised nature of the healthcare system, which is a blend of multiple public payers with a mix of entitlement and eligibility programmes, and multiple private third party payers that compete for business. For manufacturers, the US market represents the largest market opportunity for most products and has the most stakeholders impacting the reimbursement process. Manufacturers must understand the payer mix for their product relative to the payer mix for the US market to assure that the reimbursement strategy aligns to the particular payer sector that will be the most prominent decision-maker.

The challenges facing companies selling to the largest EU countries are described in **chapter 2**. In Europe, reimbursement systems vary between each country and different systems are applicable to private and public healthcare, to different product categories and even to different regions of the same country. In addition to this the goal posts are ever moving, as countries reform and restructure their healthcare provision. Germany, the largest EU market, is getting to grips with The "Law for Enhancing Competition in the Social Health Insurance System", which came into effect on April 1, 2007. With regard to the traditional structure and organisation of Germany's healthcare system the reform contains some of the most far-reaching measures of recent healthcare legislation and it is likely to have considerable long-term effects on the medical device market in Germany.

Two other major European markets, France and the UK, are getting to grips with new systems for reimbursement coding, which will have a significant effect on purchasing, particularly of more expensive medical technologies.

The Asian markets of Japan and China are profiled in **chapters 3 and 4** respectively. In Japan, a country with one of the oldest populations in the world, healthcare resources have been stretched for many years, leading to various attempts to curb spending. What's more, Japan sources most of its medical technology from indigenous suppliers. Despite this, the sheer size of the market and the country's return to economic growth make it increasingly attractive for foreign suppliers. There are still a great many hurdles to selling products in Japan. Companies have argued, however, that selling to Japan will become increasingly expensive with the new Market Authorization Holder system, which requires companies to appoint a separate body to control safety of marketed products. What's more the regulatory approval system in Japan is one of the slowest in the world.

The Chinese market will be the largest in Asia within the next 10 years so manufacturers cannot ignore this opportunity. However, access to this market is very difficult due to the size of the country and the complexity of the regulatory and reimbursement systems. Pricing of medical devices in China is primarily up to the manufacturer but government agencies and provincial bureau are starting to put into place more rules and regulations to limit prices all the way through the chain from the manufacturer's price to the end user price; in many cases the patient pays for the device.

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