CLINICA REPORTS

Global Trends in Reimbursement of Medical Technology

By

Judy Rosenbloom, Jo Ellen Slurzberg, Brian Lovatt, Alan Wilkinson, Kevin Sullivan and Duncan Fatz

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Clinica Reports

Telephone House
69-77 Paul Street
London
EC2A 4LQ
UK

Tel: (+44) (0)20 7017 6859
Fax: (+44) (0)20 7017 6975
Email: clinica.reports@informa.com

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.

ABOUT THE AUTHORS

JUDY ROSENBLOOM

jr@1jra.com

+1 818 344 4380

Ms Rosenbloom is founder and president of JR Associates, a medical reimbursement consultancy that provides coding, coverage and payment strategies for device manufacturers, venture capital firms and healthcare practitioners worldwide. Ms Rosenbloom has spent over a decade working with a variety of medical specialties on optimizing reimbursement outcomes for innovative medical devices. Ms Rosenbloom has also conducted reimbursement training programmes, is a frequent speaker at national conferences and has authored coding reference publications that help clinicians improve their coding practices.

Prior to founding JR Associates, Ms Rosenbloom was co-founder and vice president of a company that managed and delivered cardiovascular, ultrasound and general imaging services to networks of hospitals and physician practices.

She is a former executive board member of the American Society of Echo (ASE) and was named ASE's coding and reimbursement consultant in 2005. Currently, she is on the industrial advisory board of USC's Medical Device & Diagnostic Engineering graduate programme. Ms Rosenbloom is a past president of Women in Health Administration of Southern California and former board member of the American Heart Association/Los Angeles. She is a registered adult and paediatric cardiac sonographer. Ms Rosenbloom is co-author of the US chapter.

JO ELLEN SLURZBERG

joellens@almyrainc.com

+1 978-264-2004

Ms Slurzberg joined Almyra, a private international medical device holding company, in June of 2004 as vice-president. She is responsible for worldwide strategic reimbursement, health policy, and business development for the portfolio of medical devices and companies supported by the holding company. Prior to joining Almyra she was part of the executive consulting team at Boston Healthcare Associates, serving as vice-president of consulting, leading the strategic reimbursement practice, consulting to the medical device, *in vitro* diagnostics, pharmaceutical, and biotechnology industry, as well as to various investment banks and venture capital firms. Ms Slurzberg began her career in the life sciences industry in 1983 in sales and marketing and has specialised in reimbursement and health policy since 1992. She has experience in both US and EU reimbursement and has a track record of achieving coverage, coding, and payment for innovative products.

In 2006, Ms Slurzberg was elected to serve on the board of directors of the Medical Device Manufacturers Association (MDMA) and she chairs the MDMA Reimbursement Task Force. She has conducted training programmes and authored publications on general reimbursement, including two Harvard Business School Notes with Professor Regina Herzlinger. She speaks frequently on reimbursement related business planning and development topics. Ms Slurzberg is co-author of the US chapter.

ALAN WILKINSON

Alan has worked as an independent healthcare researcher and writer since 1998. He specialises in providing information services and business analysis to support new product development and international market access for a wide range of healthcare clients. From 1973 to 1994 he worked in new product development and marketing management roles for multi-national corporations in both the pharmaceutical and medical device sectors. His practical experience in the device arena spans ophthalmological implants and equipment, speciality surgical devices and vascular diagnostic equipment. Alan entered the medical information industry in 1994, working in business management roles with PJB Publications and its subsidiary Brookwood Medical Publications.

In late 2006 he spent a brief spell on assignment in Japan, gaining first-hand knowledge of the Japanese healthcare system. Alan is the author of the Japan chapter.

BRIAN LOVATT

Brian studied medicine and pharmaceutical sciences at Manchester university and then moved into the pharmaceutical industry where his career spanned over 25 years working in clinical research and development and then into sales and marketing. Finally, Brian held senior management roles, responsible for business development, health economic outcomes, pricing and reimbursement across the business.

Brian was the first international industry based health economist developing some key methodological approaches to multi-country study data collection and analysis. Brian has been involved in co-authoring the health economic guidelines in the UK and, in addition, has been involved in developing and reviewing the health economic and health technology assessment guidelines in Australia, the US, Canada and numerous European countries.

Some 12 years ago, Brian created a sophisticated expert system and model for pharmaceutical pricing and reimbursement. This system is used today by several of the largest pharmaceutical companies and also forms the basis that a great many other companies use to determine price for their products.

Brian left the industry 10 years ago, from the position of global director responsible for all pricing, reimbursement and outcomes/value support. He now runs the international consultancy practice Vision Healthcare, an industry leader in pricing/reimbursement and strategic health economics.

Brian is author of the chapter on China.

KEVIN SULLIVAN

Dr Sullivan is an economist specialising in the reimbursement of medical devices and pharmaceuticals in Germany, health economics and pharmacoeconomics and the development of strategies for introducing new medical technologies. He was formerly a senior consultant with Quintiles Consulting and is based in Germany. Dr Sullivan is author of the Germany section.

DUNCAN FATZ

Duncan Fatz is an independent healthcare consultant and writer, who has specialised in medical devices for over a decade. Based in the UK, he is the author of a number of Clinica's best-selling reports, including EU Pricing and Reimbursement for Medical Devices and Diagnostics (2006), from which the France, Italy, Spain and UK sections have been sourced and updated.

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