Mind the gap: Japan makes moves to reduce device lag

Dr Takeo Morooka

The Japanese government this month introduces a new mechanism that aims to expedite product approval and launch in the world's second largest medtech market, writes Dr Takeo Morooka, Chair of STM Committee of the Tokyo-based American Medical Device and Diagnostics Manufacturers' Association

As the rapidly ageing population puts a tighter squeeze on cash-strapped healthcare payers, the medical device industry in Japan continues to face a grim economic environment.

Ever-growing healthcare costs are indeed a looming problem for Japanese society, with the latest total health expenditure figure (2009) at ¥36 trillion ($400bn). Pressure to contain costs has continued to escalate over the past decade, with the country's Ministry of Health, Labour and Welfare (MHLW) reducing the growth of the national health insurance budget by cutting reimbursement rates.

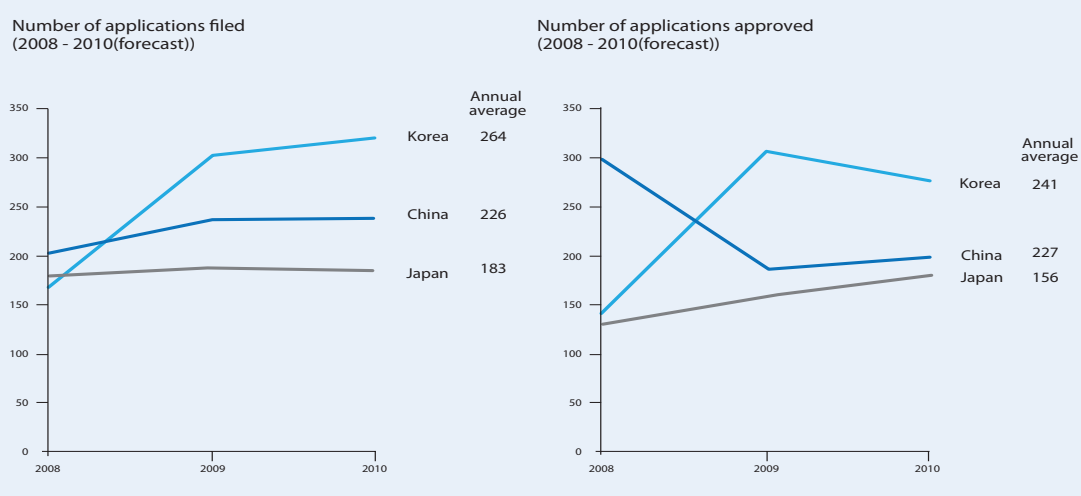
Medical devices were, of course, no exception. Special Treatment Materials (STM) – a group of devices mostly consisting of consumables and implants – had their reimbursement prices reduced on average by approximately 5% in the 2012 revision, as was also the case in 2010. This has been steadily sapping the vitality of the industry.

The American Medical Device and Diagnostics Manufacturers' Association (AMDD) has long argued that device lag and device gap are two of the most pressing issues facing the healthcare system that the government should tackle. Device lag – the delay in approval of new medical devices between Japan and the US/Europe – is between 3-5 years on average. Device gap refers to how advanced medical devices used worldwide are not made available in Japan, due to a lack of proper evaluation and review schemes for innovative medical devices. As a result, patients in Japan are denied access to the latest medical technologies.

A study conducted by AMDD and LEK Consulting in 2011 revealed that most medical device manufacturers still see significant business opportunities in Japan, at least in the near-term, despite concerns regarding relatively low market growth and cumbersome regulatory requirements. On the other hand, based on an analysis of regulatory submissions and approvals over the past three years, Japan is lagging behind not only the US and EU countries, but surprisingly also China and Korea (see Fig 1) in the launch of innovative medical devices.

However, a new rule, which comes into effect this April, is opening up opportunities for industry. With this rule, new devices with a relatively short submission delay from the US, which is associated with a narrower US-Japan ➤ p15

Fig 1. Graphs showing the number of product approval applications filed and approved in Japan, Korea and China



Note: n: submittals=14 companies, approvals=13 companies

Source: 2011 Asian Priorities Survey, L.E.K. Analysis

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device gap, will get premium reimbursement as an incentive. Specifically, this reimbursement mechanism means that new products for which

1) the lag between US FDA submission and Japanese Pharmaceuticals and Medical Device Agency (PMDA) submission is less than 180 days, and
2) the time spent by the applicant company during the PMDA review process is less than 150 days for fast-track-reviewed new products/improved products with clinical or less than 240 days for other new products, will get premium reimbursement for the first two years on top of their C1/C2 prices, at 50% of total supplementary premiums (similar category comparison method) or at additional 5% of C1/C2 price (cost accounting method).

The MHLW is in the fourth year of a five-year "Action Program to Speed-up Medical Device Approval" in order to reduce the lag, mainly by strengthening the PMDA's application review capacity. However, this reimbursement revision marks the first time that the government has deployed a reimbursement incentive scheme in its drive to improve market attractiveness and to reduce lag.

There were also other positive changes to the STM reimbursement rules, regarding how the MHLW will evaluate "increased usefulness" of new devices, as compared with existing devices with similar functions. However small the overall financial impact may be in the beginning, the industry is cautiously optimistic in seeing such changes. With further improvements in future revision cycles, Japanese patients and clinicians will have improved access to innovative medical devices over the long run.

AMDD recently stated to the MHLW that towards the next reimbursement revision cycle in 2014, industry representatives and medical device experts should be given more opportunities to speak at the Chuikyo (Central Social Insurance Medical Council) meetings, where crucial discussions and decisions regarding reimbursement take place.

There are still some unfavourable reimbursement rules remaining, notably the Foreign Average Price–based price reduction mechanism. Here, reimbursement prices are capped at 1.5 times the average prices of similar devices available in four comparator countries (US, UK, Germany and France), where their comparator prices in yen tend to fluctuate along with changes in foreign exchange rates. Without having any mechanism to raise reimbursement prices, there is no way to duly reflect the actual changes in costs for domestic sales when the exchange rates become unfavourable. A fifth comparator country, Australia, was added as of April 2012, thus further reducing the predictability of reimbursement price cuts. This results in irregularity in the device business environment and cause innovation to atrophy. AMDD continues to be fully committed to playing a leading role in leveraging advanced medical technologies for better healthcare delivery in Japan.

