

# The “device gap” means Japan’s market remains a challenge for industry



Dr Makoto Tamura

Industry has been lobbying hard to effect changes that would make Japan a more favourable market for medical technology companies. Considerable progress has been made, but key challenges remain, as Dr Makoto Tamura, chairman, STM (special treatment material) committee, American Medical Devices and Diagnostics Manufacturers' Association (AMDD) tells *Clinica*

The medical technology industry in Japan continues to face a challenging environment. In the past 12 months, however, the industry has seen some government movement on, and recognition of, issues which the industry has been bringing forward to the government for a long time.

These include supply stability, reimbursement and eliminating the device lag/gap. While the industry appreciates recognition from the government, action is urgently needed to solve these issues to allow patients and medical practitioners in Japan access to superior medical technology without delay.

## Huge device gap exists

The medical device market in Japan is facing a difficult situation. According to an American Medical Devices and Diagnostics Manufacturers' Association (AMDD) study, approximately half of the medical devices available in the US and the EU are not available in Japan.

The device gap denies patients access to the latest medical technologies in Japan. Also, as a result, a stable supply of products is threatened. In 2009 the industry faced various product supply shortages.

## Background to the device gap

There are two reasons for the device gap: the device lag (submission delay and review delay) and the manufacturers who choose not to submit products for review/approval.

In an effort to eliminate the device lag, the government of Japan launched the 'Action Program to Speed up Medical Device Approval' at the end of 2008.

The programme includes increasing the number of Pharmaceuticals and Medical Devices Agency (PMDA) reviewers to 104 by 2013 and a 'Three-Track Review System,' which includes tracks for completely new, improved and generic (or 'me-too') medical devices, with separate review teams specialising in each track.

Such changes are expected to go a long way to shorten the review period, a major influencer on the device lag. A reduced review time will increase the speed in which the industry can supply medical devices to patients in Japan

## Manufacturers choosing not to submit

The industry believes the imbalance among reimbursement, regulatory rules, and the volume and structure of the market are

the root causes of manufacturers choosing not to submit medical technology for review/approval.

In the past, Japan's reimbursement level was higher than other countries, though the regulatory hurdle was quite high, and the market was fragmented.

However, the device reimbursement price in Japan has decreased significantly and is becoming closer to the price seen in other countries.

In some cases, the reimbursement price of products is lower than in other countries. If regulatory rules and market structure are not drastically changed, the reimbursement price in Japan needs to be relatively high compared with other countries, otherwise the device gap will continue to grow, and achieving a stable supply of products will become increasingly difficult.

## Reimbursement system

To improve the above mentioned serious situation, the industry firmly believes that the current reimbursement rules should be changed, for example, by abolishing the Foreign Average Price (FAP) rule.

However, for the past 8-10 years the government has been trying to reduce the growth of total healthcare expenditure as much as possible, as it has huge debt compared to other countries.

The new administration, Democratic Party of Japan (DPJ), committed itself to increasing total healthcare expenditure during the last election, and is to bring about the first rise in reimbursement in 10 years with the reimbursement revision, set for April 2010. However, budgets for devices/drug were still reduced.

## Economic growth strategy

The DPJ announced a new economic growth strategy at the end of last year. A major strategy is the promotion of the healthcare industry.

The announcement of the details of this strategy is expected in a few months, and the industry is hoping that it will be helpful in improving the medical device market environment.

The industry will continue to insist on improving the market environment for reimbursement as well as regulatory issues.

Then it will be able to maintain a stable supply and provide patients and medical professionals in Japan with the latest medical technology, which is the overall mission of device companies.

• To contact the AMDD, go to [www.amdd.jp](http://www.amdd.jp)