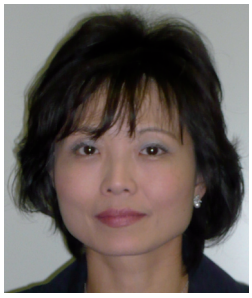
Japan's device lag could be a thing of the past

Japan has come under fire from industry for its slow approvals system for medical devices compared to that of the US. But, as Junko Kodama, chairman of the regulatory affairs and quality assurance (RAQA) committee at American Medical Devices and Diagnostics Manufacturers Association (AMDD), explains, "momentous changes" are underway to change the system for the better.



Junko Kodama

Currently, approximately half of the medical devices available in the US and the EU are not available in Japan.

This unfairly denies Japanese patients access to the best technology currently available. Medical devices and diagnostics critical in the diagnosis and effective treatment of diseases should be available to patients all over the world.

For various reasons, however, there are great differences in the access to medical devices even among industrialised countries. The delay in providing medical devices in Japan compared with access to the same devices in Europe and the US is referred to as the device lag.

The tables below show the difference in the total review period between Japan and the U.S. for new medical devices and in-vitro diagnostics (PMA equivalent products) and others (510(k) equivalent products) which were approved in Japan between 2006 and 2008 (Fig.1 and Fig. 2).

While Japan's review period is improving; a significant lag remains. The average total review period for medical devices and in-vitro diagnostics for PMA equivalent products in the US between 2006 and 2008 was 10.1 months, while it was 21.1 months in Japan. In addition, the review period for 510(k) equivalent products was 14.3 months in Japan, while it was only 2.2 months in the US.

In an effort to eliminate the device lag, the Ministry of Health, Labour and Welfare (MHLW) announced an action programme to accelerate the approval process of medical devices (excluding IVD) on December 11, 2008. The plan aims to speed up the system by:

- improving efficiency of the review processes by increasing the number of reviewers, and improving their training
- adopting a three-track review system for 'new', 'improved' and 'me-too' medical devices
- setting performance goals

"I was able to see first-hand that a momentous change is on the horizon"

Reviewer numbers to rise

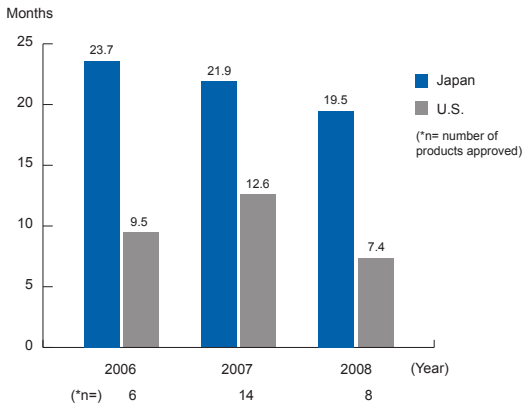
The number of reviewers will gradually increase from 35 (as of March 2009) to 104 by 2013 (although review fees were increased in April 2009).

In April this year, I was invited by the Pharmaceuticals and Medical Devices Agency (PMDA) to present at a training seminar for 140 new employees including eleven new reviewers. I was able to see first-hand that a momentous change is on the horizon and I have high hopes that the training programme will fulfill its function to reduce inconsistencies among review categories and reviewers.

Adoption of a three-track review system is expected to go a long way in shortening the review period. The single track system reviewed 'new', 'improved' and 'me-too' medical devices together and it was suggested that this was one factor contributing to the device lag.

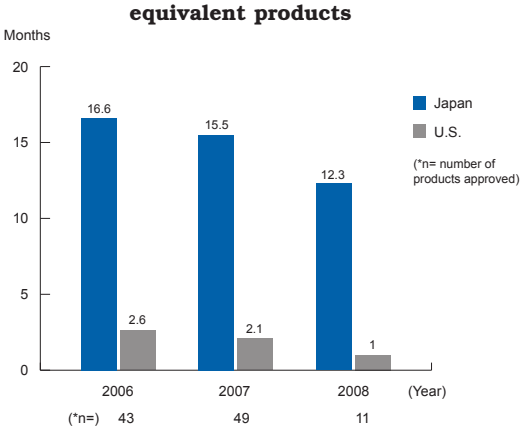
In 2008, the American Chamber of Commerce in Japan (ACCJ) and the US medical technology association,

Figure 1: Changes in the review period for PMA equivalent products



Source: "2008 Device Lag Study" by the American Chamber of Commerce in Japan (ACCJ)

Figure 2: Changes in the review period for 510(k) equivalent products



Source: "2008 Device Lag Study" by the American Chamber of Commerce in Japan (ACCJ)

Table 1: Target review periods (median approval cohort), in months							
		Actual	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
New device	Normal	Approx. 21	21	21	20	17	14
	Priority	Approx. 16	16	16	15	13	10
Improved Device	Clinical Trials	Approx. 16	16	16	14	12	10
	Without Clinical Trials	Approx. 11	11	11	10	9	6
Me-too device (with approval standards)		Approx. 8	8	6	5	4	4

AdvaMed, submitted recommendations to the MHLW regarding methods to improve the review system.

Establishing performance goals for the review process was the most remarkable development

The recommendations included 'least burdensome approach', an approach adopted by the US, in which both the reviewer side and applicant side must use whatever reasonable means available to reduce the review period while ensuring the safety and effectiveness of the medical product being evaluated. The recommendations were subsequently accepted.

Establishing performance goals for the review process (see table below) was the most remarkable development. This is the most significant achievement in 24 years since the standard review period for new medical devices was set to one year, after the US – Japan MOSS (market-oriented sector selective) negotiations in 1985.

The government and the medical device industry have agreed to track the progress of the action programme on a regular basis, starting this Autumn. Achieving these performance goals will not be easy. This is, however, the beginning of a cooperative effort between the government and the medical device industry to achieve the common objective of delivering superior medical devices to patients in Japan without delay.

For further details about the AMDD, go to http://www.amdd.jp/en.

Japan's device regulator to open up to world

Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has announced a new strategy to play a greater role in the international community.

In its "International Strategic Plan", the PDMA says it intends to strengthen cooperation with the US, the EU and Asian countries as well as various international bodies.

The PMDA said it would regularly invite personnel from the US FDA and Europe's EMEA to its offices and establish a system to exchange information and opinions. "The PMDA will swiftly analyse, evaluate and translate important overseas information and communicate it to the relevant parties," the strategy report says.

Where Asian countries are concerned, the PMDA intends to focus on building relations with China and South Korea. Staff will be encouraged to take part in exchanges with personnel at China's State Food and Drug Administration (SFDA) and Korea's Food and Drug Administration (KFDA) to share information on product evaluation and safety measures.

On the international level, the agency will proactively send its directors and staff members to meetings on international harmonisation, and strengthen relations with international bodies such as the World Health Organisation (WHO) and the Organisation for Economic Co-operation and Development (OECD).

The agency also plans to improve its English website and offer more translations of its documents and reports and to open up more to the media. As part of this strategy, it intends to give lectures and grant interviews to the Foreign Correspondents' Club of Japan and other representatives of overseas media.

Japan/US joint report on device commitments

The Obama Administration has secured commitments from Japan to improve its reimbursement and regulatory practices for medical devices, an 86-page report reveals.

It includes a commitment to increase reviewers and track the performance of those reviewers against performance goals and to publish the results

The joint report between the US and Japanese governments was presented to US President Barack Obama and Japanese Prime Minister Taro Aso on July 6.

It includes commitments from the Ministry of Health, Labour and Welfare (MHLW) to:

- continue to provide US industry with opportunities to express views on the Foreign Average Price (FAP) rule, and to consider those views "necessary";
- allow industry to express its views on the R-Zone (a method which compares domestic market price data with the current reimbursement rates) with the MHLW recognising the unique nature of medical devices and innovation;
- continue to provide US industry opportunities to discuss the cost of doing business in Japan and continue discussion on premiums towards the next medical device pricing revision;
- continue discussions with industry on the speedier introduction of C1/C2 products; and
- continue to consult with industry on the reimbursement pricing process, including that for C2 applications.

"We applaud both governments for their efforts to improve access by Japanese patients to life-saving and life-enhancing technologies," AdvaMed president and CEO, Stephen Ubl, said.