



# **Issues Regarding to Medical Device Market and Idea of Solutions**

- Proposals to realize better healthcare in Japan -  
**AMDD internal reference**

American Medical Devices and Diagnostics  
Manufacturers' Association (AMDD)

June 2011

# Contents

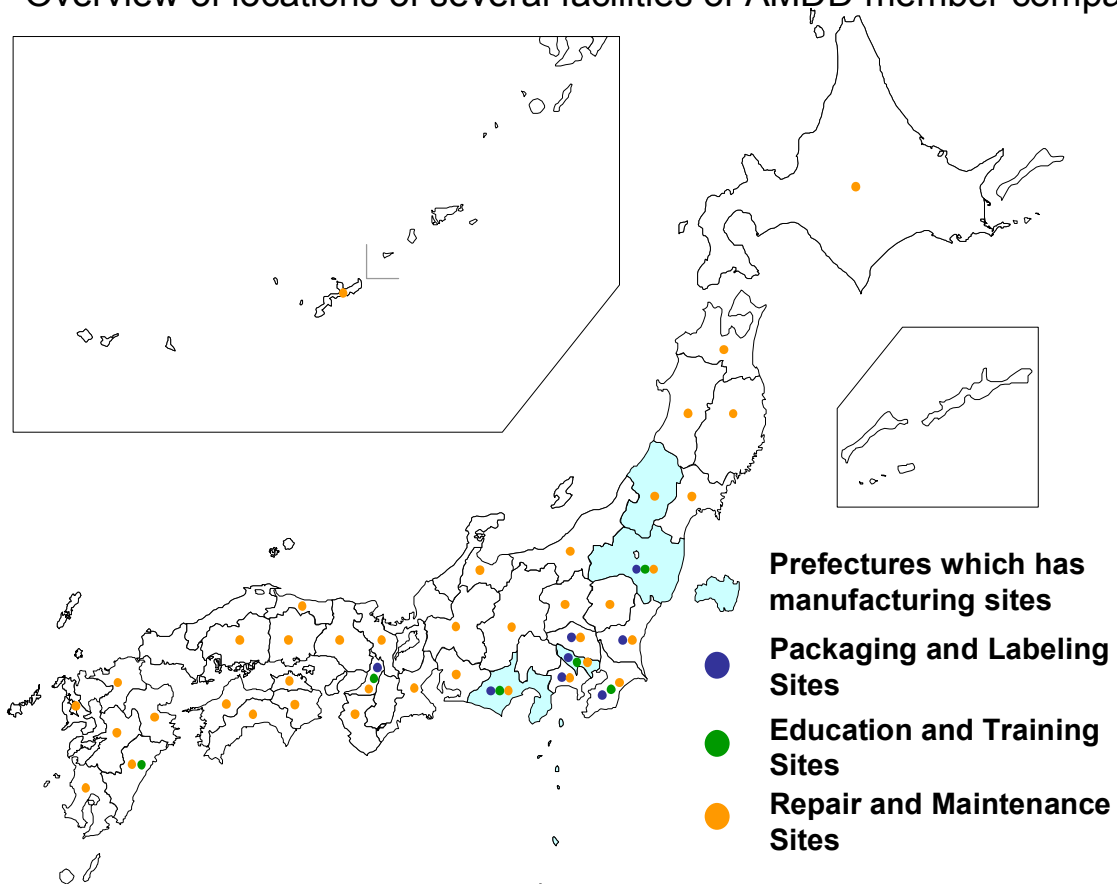
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# About The American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) is an industry group organized by 67 Japanese entities which have their headquarters in the US or which sell products in the U.S. offering advanced healthcare technologies such as medical devices and/or in-vitro diagnostics (IVDs) in Japan. The AMDD was established on April 1, 2009, after years of activities as the Medical Devices and IVD Subcommittee at the American Chamber of Commerce in Japan (ACCJ). Average business operation years of those member companies in Japan is 27 years and are generating approximately direct 21,000 employments (as of July 2010), contributing developments of local economies. .

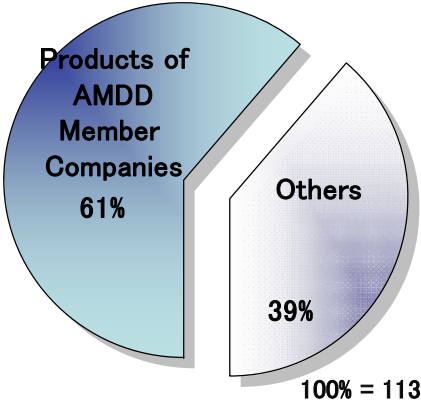
## ◆ Overview of locations of several facilities of AMDD member companies



The direction of AMDD is, primarily to meet needs of Japanese patients and medical professionals by delivering new medical technologies (both therapeutic and diagnostic). We are contributing to introduce advanced medical technologies that are considered global standards as early as possible, especially offering therapies and diagnosis for orphan and intractable diseases and improving patients' QOL. Further, we want to maintain stable supply of medical devices to the field as we offer safer, more effective, and less invasive products to the market.

AMDD member companies are striving to realize high level of medical cares in Japan by introducing innovative and global standard medical technologies which include: cardiovascular devices such as pacemakers, ICDs, artificial valves, PCI catheters; orthopedic devices such as artificial joints; stent grafts; intraocular lenses; laser surgery device; large imaging devices such as CTs and MRIs; genetic diagnosis, IVD and systems, etc., to this market. It is noteworthy that, during the 5-year period (2005-2010), 61% of "new medical devices" approved in Japan were from AMDD member companies.

◆ New Medical Devices Approved in Japan



PMDA data (Heisei 17 to July of Heisei 22)

In addition, AMDD member companies markets variety of products which were developed and/or improved based on the ideas at Japan, Example of those products are; orthopedic devices such as artificial joints, trauma implants, spine fixation devices; cardiovascular devices

such as guide wires, small heart valves, micro catheters, MRI, CT, contrast media auto injectors, adhesive bandages, whitening agents, and urine collection bags. Also, products developed and manufactured by Japanese companies are widely used in our products, in the area of manufacturing equipments, electronic components, precision machinery components, precision plastic moldings, as well as specialty products such as CT detectors, ultrasonic probes, antibodies for diagnostic reagents, etc.

We believe that we can keep contributing to the Life Innovation area of New Growth Strategy through growth of industries, expansion of economy and employments though generating new services, as well as developing and implementing of new product and technologies in Japan.

# Issues at medical devices and IVDs in Japan and proposals of solutions

Below 5 points are becoming issues not only AMDD member companies, but also Japan domestic companies. Those issues need to be solved primarily to respond needs at patient and medical field, as well as to aim steady growth of economy based on new growth strategy.

## **Issue 1: It needs quite a time in Japan to start to use new medical devices and IVDs (Device lag)**

Device lag means that medical devices are introduced later in Japan than in Europe and the U.S. Unfortunately, among Japan, the U.S. and Europe, majority of devices would be lastly introduced in Japan. Device lag itself tends to be longer (currently 3 to 5 years delay). IVD also has delayed review cycle time issues.

Acceleration, monitoring and disclosure of progress of "Action program" to expedite review for medical devices (Dec 11<sup>th</sup>, 2009)" as well as standardization of testing and reviews are to be needed.

## **Issue 2: New devices and IVDs are not introduced in Japan (Device Gap)**

Device gap means that medical devices used in worldwide will not be introduced in Japan. Not only having proper evaluation to the innovation, but also it is needed have proper review scheme according to the level of efficacy for devices for orphan and intractable diseases which might generate small size market (example: US HDE scheme)

Doing Shonin evaluation which align with Japanese medical field, and, proper reimbursement evaluation scheme which recognize innovations are expected.

## **Issue 3: Decision of reimbursement is not align with Japanese market, and very difficult to forecast**

FAP (Foreign Average Pricing) scheme The scheme to reduce the price difference between Japan and foreign countries, which was seen as an issue in 1990's, by using average price of US, Germany, UK and France. The foreign price difference has been reduced in the past decade, and current drastic change of foreign currency exchange rate will worsen device lag, gap and stable supply if we maintain this scheme.

The role of FAP scheme had been well accomplished so abolishment of this scheme is appropriate.

## **Issue 4: Reward of innovation by reimbursement for new medical device is not adequate to promote innovation**

To resolve device gap and to foster medical device industries in Japan, proper and transparent evaluation scheme is needed for innovations. On the other hands, for STMs (Special Treatment Materials), even when the costs to introduce devices and to operate businesses in Japan are high compare to foreign countries, the ratio of Japan price to the foreign average price is less than 1.0

Capital equipment devices are being reimbursed in terms of technology (specially calculated medical fees) not by products (specially treated materials). This it is not easy to have proper reimbursements for capital equipments after modified or improved. We require the introduction of new evaluation system to accelerate modifications, improvements and development of new device

Since IVD doesn't have reimbursement scheme which reflects clinical values and cost, there is an issue that it takes longer time to replace old technologies by new technologies. It is necessary to build reimbursement scheme which reflects clinical values and costs. Further, periodical performance review of products and pricing based on disclosed performance to be needed.

To contribute to both level up of Japanese healthcare and innovation of technologies for medical devices and IVDs, proper rewarding of innovation to reimbursement is necessary.

**Issue 5 Safety management for capital equipments is not adequate**

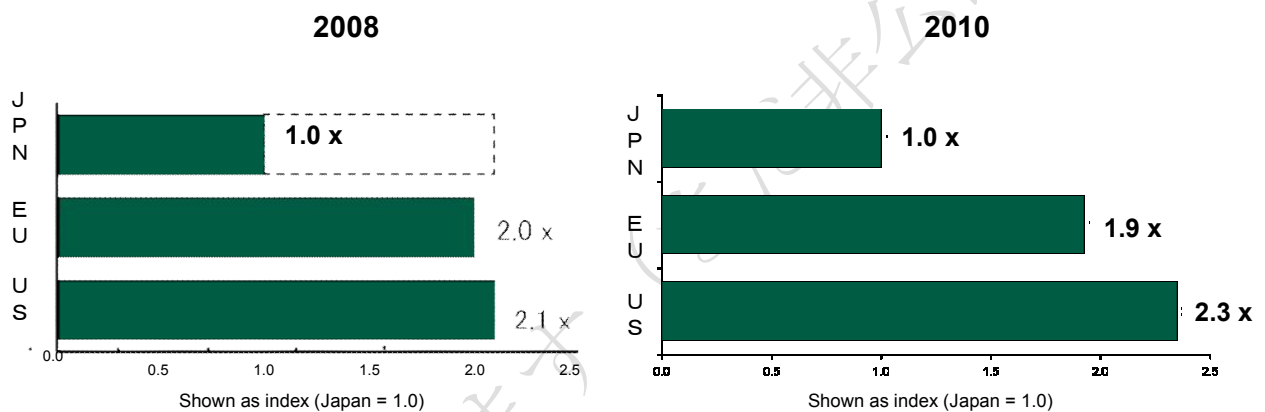
Maintenance of important capital equipments are not adequately conducted. To ensure appropriate safety control of medical devices, raise awareness among medical institutions which had been defined by Medical Service Law and Pharmaceutical Law, as well as sufficient incentives for hospitals for that are needed.

Upgrading of quality in healthcare, mitigating avoidable accidents and injuries, and higher efficiency in medical expenses are three targets that can be achieved by aiming at reducing unpredictable accidents, injuries, and predictable infection risk, and by arranging comprehensive guidelines, laws, and regulations for improving safety for patients as well as medical professionals.

# Situation of Device Lag and Gap

“2010 cycle time survey” conducted by the AMDD disclosed that numbers of medical devices available in Japan is less than half compare to EU and U.S. Comparing to survey conducted 2008 revealed that the difference to U.S. is bigger. Those devices not available in Japan will be categorized either to be introduced later (device lag) or never introduced in Japan (device gap). As of developed country, existence of device lag, device gap and stable supply issue followed them in Japan, as advanced healthcare country, would be a concernment matters.

◆ Medical devices available used in Japan is about half of Europe and less than half of U.S.



Source: ACCJ 2008 device lag survey. Based on 43 companies data, consists of 33 US companies and 10 EU companies

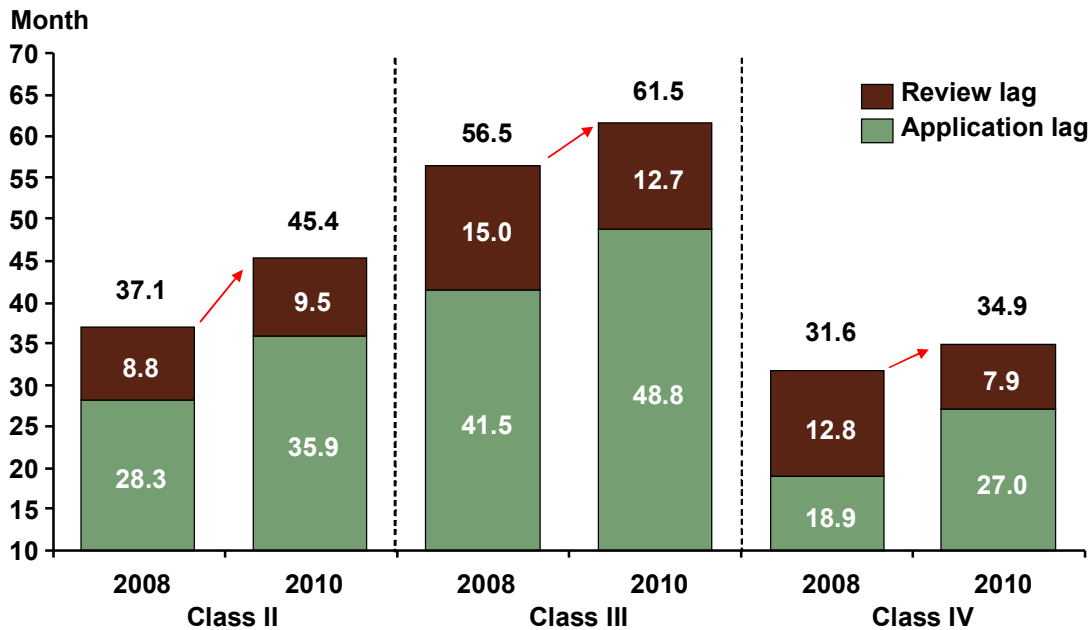
Source: 2010 AMDD time clock survey by LEK. Based on US and EU companies

Device lag can be attributable to the longer time required for both submission as well as approval process in Japan compared with Europe and the U.S. The survey examined two periods of time: from development to submission (before filing), and from submission to approval (after filing), and also compared such periods with the previous data collected by the Pharmaceuticals and Medical Devices Agency (PMDA). As the results, the period from submission to approval was reduced, might be due to the “Action Program” to accelerate review cycle time for medical devices. However, period from development to submission was not reduced, thus, consequently, there was still a serious device lag.



◆ Device lag tends to be expanding (Especially application lag)

<Device lag by classification (Comparison to The USA)>

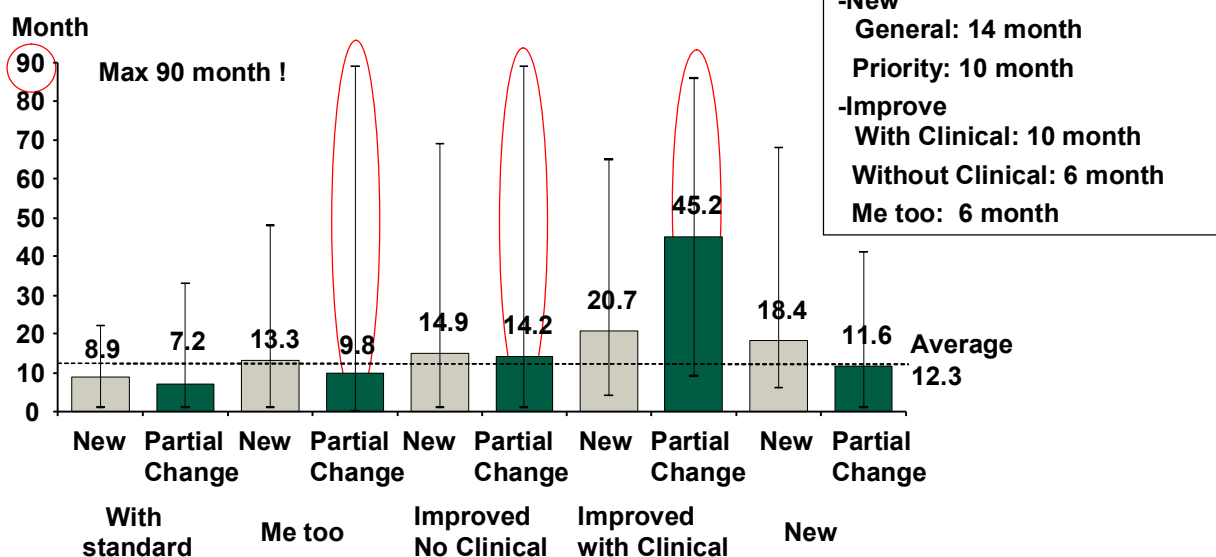


Source: Time clock survey for medical device (2008 and 2010. Survey conducted on 2010 was joint survey with JMED and EBC), analyzed by LEK

Survey disclosed the wider range of distributions in the review cycle time.

◆ Large deviations are seen in review times

<Situation of review time>



Source: Time clock survey (2008/2010年) and PMDA Action program

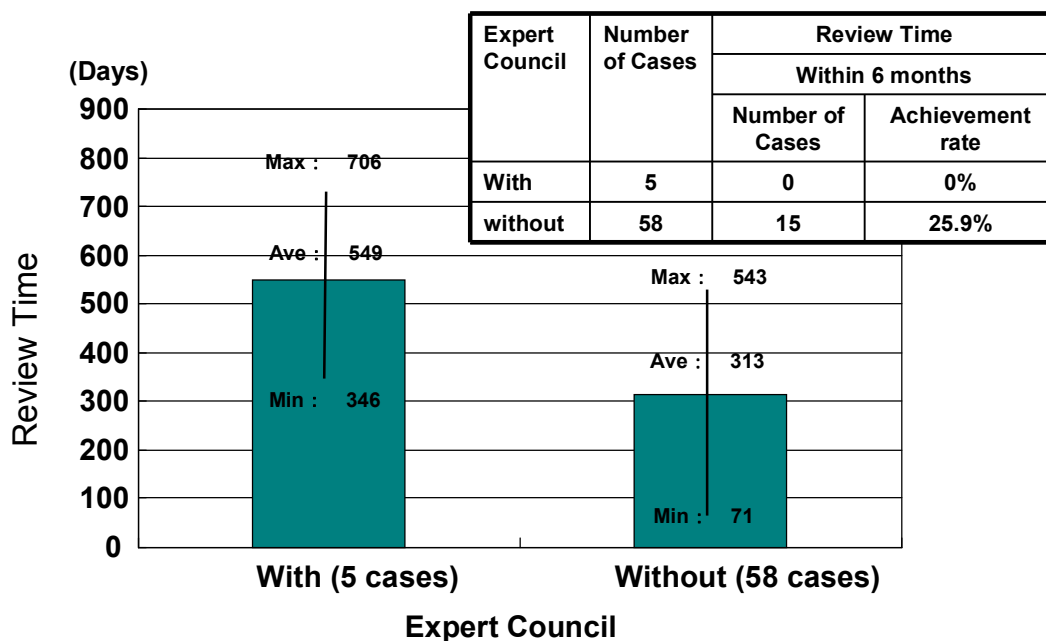
There is the situation that IVDs, based on latest technology available in global, can not be used in Japan. IVDs need review in accordance with the Pharmaceutical Affairs Law before manufacturing/import/distribution in Japan, as with pharmaceutical products and medical devices.

After amendment of the Pharmaceutical Affairs Law in 2005, important steps have been taken toward providing a better direction; for example, regulations were taken according to risk, and a system for early provision to markets was constructed after three-class categorization: approval, third-party authentication, and notification (self-authentication). It is encouraging that IVD-related topics have been introduced in the New Innovative Medical Device and Technology Industry Vision of the Ministry of Health, Labor and Welfare. In reality, however, things have not advanced sufficiently. Particularly, there are issues such as the following in terms of the review of new products requiring approval by the Minister of Health, Labor and Welfare. We think we need to improve situation that Japanese patients cannot be tested by IVDs based on the latest technology, and in some cases they cannot receive optimal treatment based on accurate test results.

◆ Approval period of IVD also vary widely

<Achievement rate is only 25.9% (15 cases) in IVD items

(58 cases which approval period is defined as 6 months>



Source: Joint survey by JACRI/AMDD (2010)

Reasons contribute having device lag and gap are the increment of practical workload at manufacturers as well as increment of difficulties for decision making due to the Japan unique regulations and reimbursement schemes regarding to medical device.

For example, difference of decision criteria that clinical trials are not required in Europe and the U.S., but they are essential in Japan, or because stability tests have to be conducted in real time in Japan, while they may be accelerated in the US for some medical devices, or development of the documents and preparations for QMS audits. Difference of workload for companies and regulatory staff is there due to the difference of the decision criteria in partial change approval, for example regulatory application would be needed in Japan but not in the US and Europe.

Device gap is not only for the foreign products

Contradiction that high performance artificial heart developed by Japanese company can not be used in Japan. There is an article regarding to the Japanese patient who had heart implant in Germany. Artificial heart which can be used in Japan under Japanese reimbursement is only external one which is called "NCVC type" developed 20 years ago. This product is not supposed to be used more than 1month since it generate thrombosis so patients need to change device many times while waiting for the order of heart implant. Patient who was in the article of Asahi news paper gathered 70M yen and came to Germany on September 2007. After 1month, his condition became worse and he needed to implant another artificial heart, which was developed by Japanese company, with having high safety and reliability. In Japan this product haven't had Shonin approval. In Germany, once new artificial heart is implanted, then priority of that patient to implant heart becomes lower. It is general to wait for 1 year, sometime several years. If one has "NCVC" one, that patient is regarded "high risk if one wait heart implant for long time". He wanted to come back to Japan but he couldn't since device he implanted was not approved in Japan. There was no warranty that he could get proper treatment once any issue happened for that device. He said he was refugee by implant.

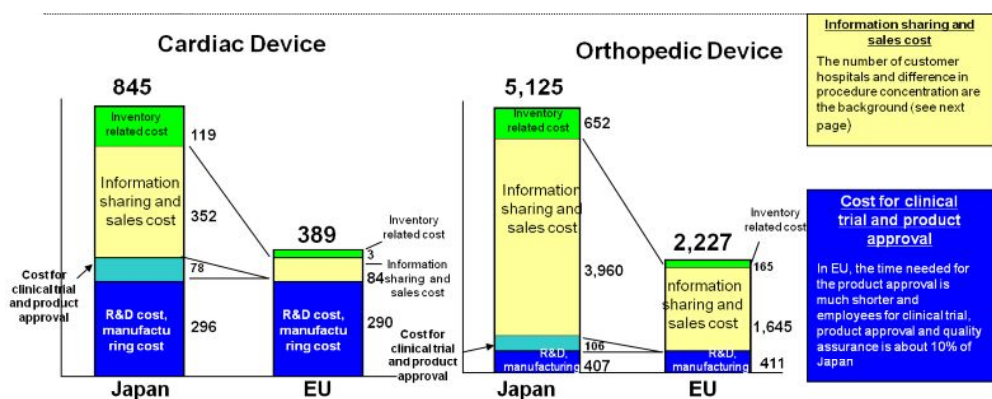
From Globe of Asahi news paper March 2010  
([http://globe.asahi.com/feature/100322/01\\_1.html](http://globe.asahi.com/feature/100322/01_1.html))

# Issues on FAP Scheme

First of all, the environment surrounding medical devices in Japan differs significantly different from that of in foreign countries. Factors, such as many requirements due to Japan's unique regulatory approval system, longer evaluation terms, difficulty of conducting clinical studies, and the many number of medical institutions for better access, with the resulting complicated distribution system and lower caseload per physician are leading to significant cost differences compared with other countries. For STMs in particular, FAP by functional category of existing devices, R-zone price reductions, and unpredictable price decision process (timing and price itself) for new devices, have effect on the decisions to introduce products in Japan, and therefore the device gap,

In 2009, the AMDD commissioned the Mitsubishi Research Institute, Inc. to conduct "A Survey of Cost of Doing Business of Medical Device in Japan compared to Europe". The survey shows that the cost to develop and marketing of medical devices is more than double compared to other countries. This naturally results in prices different from other countries for companies to make reasonable profit in the Japanese market. So taking of price high-low comparison by using just only prices at foreign country is not proper method.

- ◆ Difference of marketing cost between Japan and EU are 2~4 times, and the cost in Japan for clinical, regulatory and quality is 20 times higher than EU



Cost comparison – above is the index where R&D cost per unit (pre-clinical) in each countries is set to be 100 -

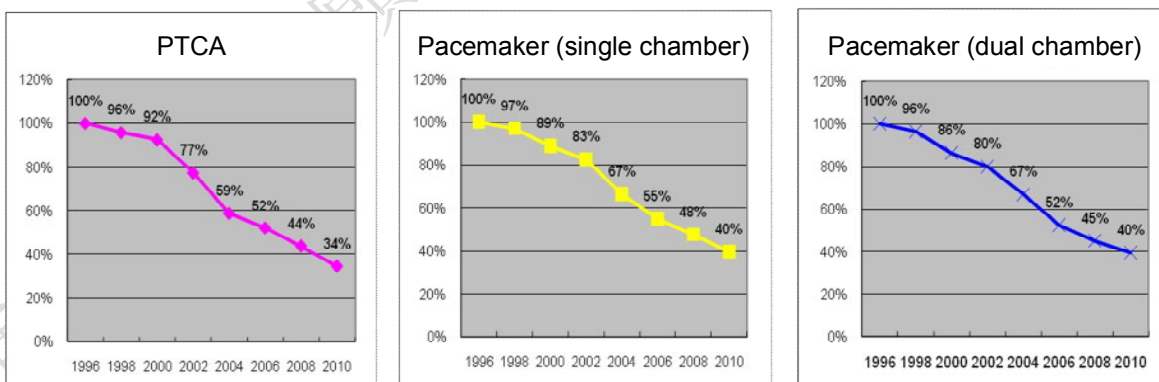
- ◆ In Japan, number of client facilities are 3 - 4 times more by one sales representative than in EU, and number of cases per hospital are 1/5 – 1/10 of EU



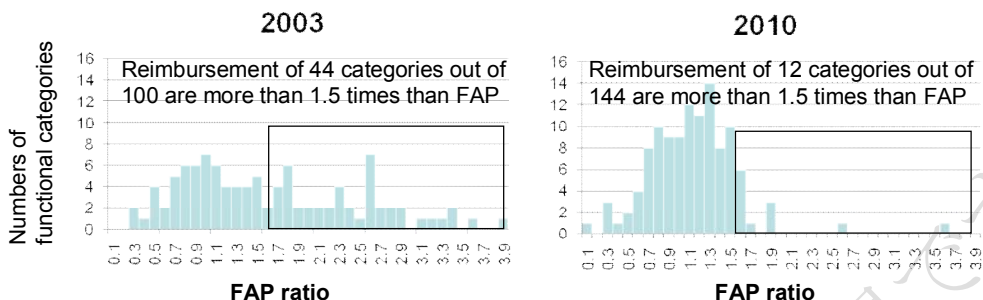
However, discussions to eliminate the medical device price difference between Japan and foreign countries have persisted for the last decade and various discussions and rule implementations have taken place. As a result, the price difference is all but resolved, we see dissolution of those differences.

- ◆ Reimbursements for medical devices dropped rapidly in past decades

<Trend of reimbursements>



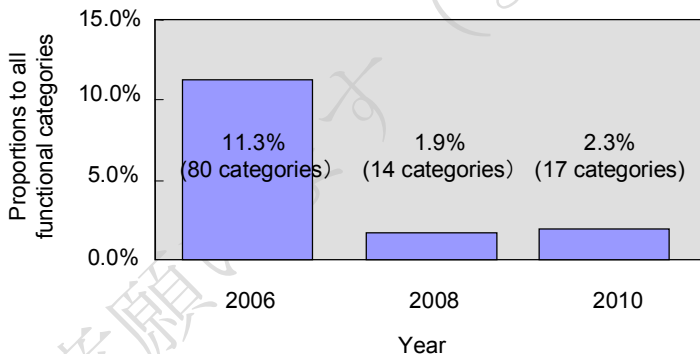
◆ Price gap reduced significantly



Source: AMDD. This survey is not for all functional categories but for categories which AMDD member companies have their products

◆ Impact of FAP scheme to price reduction is limited

<Numbers of functional categories which prices were revised by FAP scheme>



In spite of this, there is still a gap stemming from the differences in the healthcare system, delivery environment, and business practices. Especially, prices of new products tend to be lower than foreign prices because the evaluation of value of the products and cost for development, improvement and renovation, in another words, evaluation to the innovation, is not properly reflect in the price. Because of this circumstance, it is becoming very difficult to judge if return on the investment in Japan will be proper or not in longer term, and that drives device lag, device gap and further issue for stability of supply.

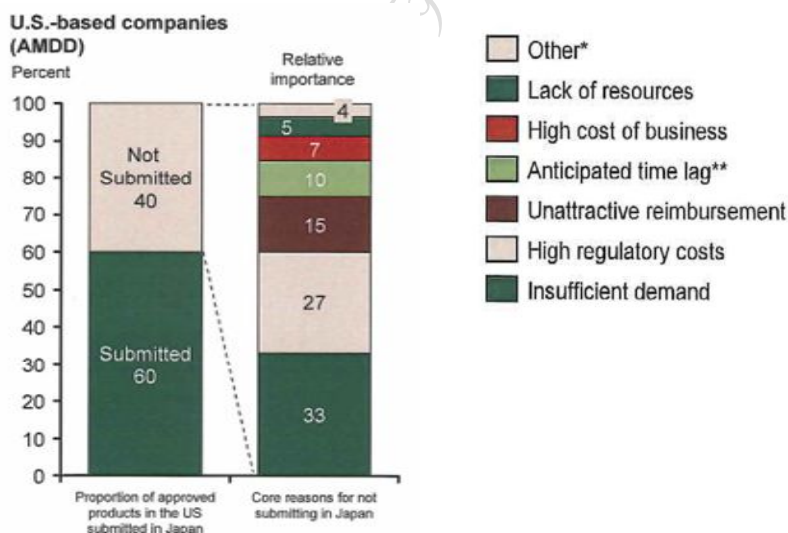
Moreover, other Asian countries are becoming more appealing markets because of their economic growth, so it takes a long time to decide in which Asian countries first, and in some cases, introduction of products in Japan becomes later than those of Asian countries.

◆ Japan tends to be a last country for the device introductions

Order	Sample		Gaps of approvals (days)		
	Size	Portions	1 <sup>st</sup> to 2 <sup>nd</sup>	2 <sup>nd</sup> to 3 <sup>rd</sup>	1 <sup>st</sup> to 3 <sup>rd</sup>
US-JPN-EU	4	0.7%	1,434	123	1,557
US-EU-JPN	155	29.1%	474	1,348	1,822
EU-US-JPN	204	38.4%	395	1,122	1,517
EU-JPN-US	9	1.7%	590	91	680
EU/US-JPN	12	2.2%	1,420	NA	NA
US-JPN	80	15.0%	2,648	NA	NA
JPN-US	1	0.2%	219	NA	NA
JPN-EU	6	1.1%	270	NA	NA
EU-JPN	62	11.7%	1,546	NA	NA

Source: Time clock survey, analyzed by LEK

◆ Reasons devices can not be introduced in Japan



Source: AMDD time clock survey (2010)

Due to these facts, we have consistently disagreed with the recalculation of reimbursement rates since the system was introduced in 2002. It involves a price's revision within a certain range if the domestic price reaches a certain level (1.5-times higher as of 2010) or higher in

comparison with the price in the US, UK, France, and Germany. There are five main reasons that we disagree.

1. As mentioned in the discussion on the difference between domestic and foreign prices, we have a drastically different environment in Japan from the environments in the countries compared regarding the introduction and distribution of medical devices. There is no point in comparing prices among such differing environments.
2. Most of the cost of supplying medical devices occurs domestically; such as readiness for compliance with regulations in connection with a country's pharmaceutical laws, providing information to medical institutes and training for physicians and other medical professionals. All costs occur domestically if a product is manufactured in the country rather than imported. Application of the reimbursement recalculation is unreasonable while it was applied under the rapidly fluctuating exchange rates resulting from the recent Lehman shock and financial crisis in Greece, because domestically occurring costs are required to be suppressed without reason even if they have no relation to exchange.
3. The reimbursement rate recalculation system has already been applied five times. Following these applications, prices were radically reduced for products that had already been singled out. Also, in deciding new prices for new products, the reimbursement rate recalculation system will no longer be useful since prices are compared with those in foreign countries.
4. Calculation of reimbursement rates is a system that significantly lacks the predictability needed for managing businesses. The system reduces the magnification ratio in comparison with relevant foreign prices, increases the number of divisions to be surveyed, causes frequent arguments about the expansion of the countries involved, and depends on exchange fluctuations. Businesses are concerned about the possibility of the system further increasing the pressure on pricing. Namely, the system makes the Japanese medical device market unattractive due to its clearly higher business costs than those overseas.
5. A great deal of labor is required and one reason of cost up at domestic and foreign offices to collect information on foreign prices.



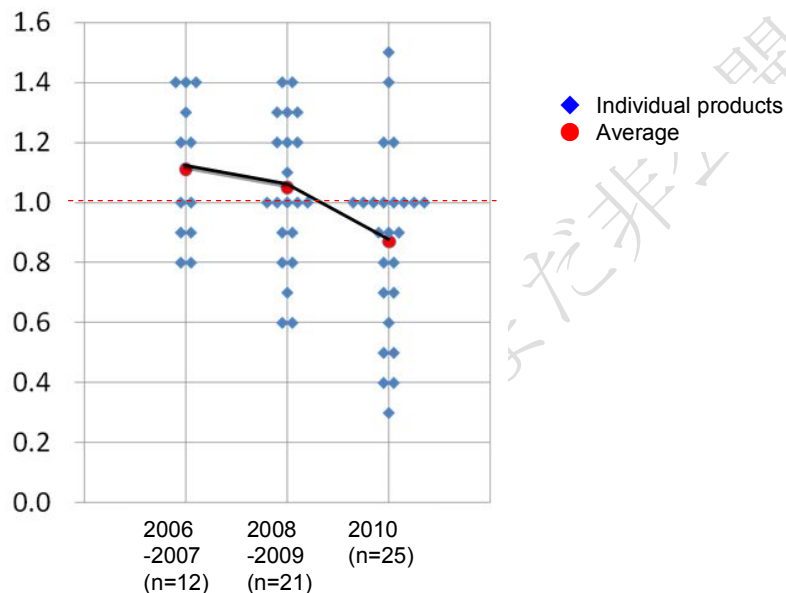
# Proper Evaluation to Accelerate Innovation

For new medical devices, as described, decided reimbursement are not reflecting cost for modification, improvement and introduction of medical devices as well as their values especially innovation, Further, reimbursements decided are tend to lower compare to foreign prices.

## ◆ FAP of new products are less than 1.0

<Price of new products via C1/C2 divided by FAPs

(Japan price is as 1)>



Source: Chuikyo. 2010 data is until Nov 2010

We request the following reforms as “evaluation of innovation” to promote research and development as well as introduction of new devices to dissolve device lag and gap.

(1) Products which approved at the category of “New medical device” and “Improved medical device” should be allowed to obtain individual brand based price.

(2) Special exceptions should be permitted when a price for a similar function category is reduced a certain level, and the similar function category system does not allow pricing suitable for technical innovations.

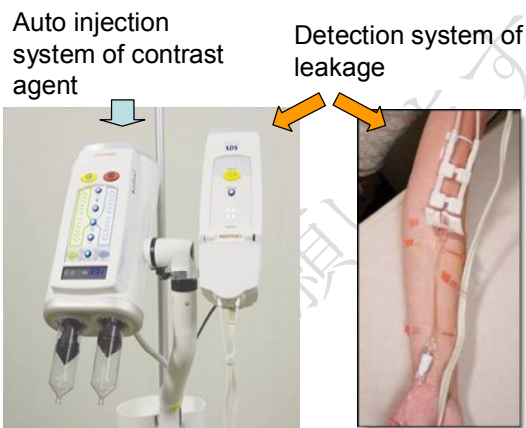
(3) The scope of cost should be clarified for cost-building scheme, for example, incorporating pharmaceutical costs, including clinical trials and PMS, concerning the cost accounting system.

(4) Allowing submission of reimbursement application and starting review of it before Shonin approval could reduce the term of Shonin application to the reimbursement listing. In addition, accelerate listing by shorten the occasion of reimbursement listing than current 3 month.

(5) Capital equipments are reimbursed by “technical fees (specific calculated medical fees)”, not by “product (specific treated materials)”. Reimbursement is not predictable due to the unclearness of definition of new technology and new function. To promote modification, improvement and development of new product, it is necessary to have new scheme,

(6) IVD is not exception. Since IVD doesn’t have reimbursement scheme which reflects clinical values and cost, there is an issue that it takes longer time to replace old technologies by new technologies. It is necessary to build reimbursement scheme which reflects clinical values and costs. Further, periodical performance review of products and pricing based on disclosed performance to be needed (For further details see References).

◆ Capital equipment doesn’t have clear process to reward innovation



Ex) Detection system of leakage of contrast reagent was developed. Leakage is expected to be happening 20,000 cases in a year. But because this is not paid by reimbursement, introduction of this useful system has not been promoted well.

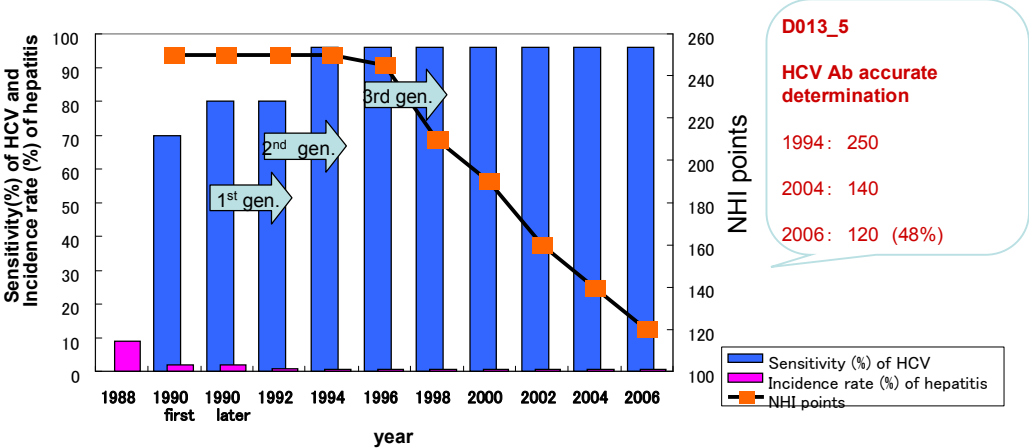
Source: Regarding to leakage, Cochran ST, Bomyea K, Sayre JW : Trends in Adverse Events After IV Administration of Contrast Media. AJR 2001 ; 176 : 1385 – 1388

# Proper Evaluation to Accelerate Innovation

◆ Issue of Innovation Evaluation in IVDs

<e.g.: Transition of NHI points for HCV Ab>

Clinical value: Mixed-cases of old and new generation IVDs, and doctors and patients face the difficulty to select/implement most relevant test which is reflected the clinical value.  
 Technology Innovation: No change of NHI points even though clinical value (product performance) improves much better, by lack of periodical review system of products in the market.



# Promotion for Safety Management of Medical Device

## **Issue regarding to capital equipment**

Since 1951, Japanese law requires all automobiles be subjected to periodic and thorough inspection and maintenance in order to ensure safety and protect Japan's citizens. Fail to comply with the "SHAKEN" system and your vehicle will no longer be allowed to operate. Similar mandatory inspection and maintenance systems exist for elevators and building boilers with universal compliance.

While a similar law exists for medical devices, there are few consequences for non-compliance. The fact is that there are a number of critical medical devices that are not maintained or serviced regularly in Japan. This results in lower productivity (downtime of equipment), increased failure rates and safety related incidents involving patients and hospital staff.

"Teikitenken" is periodically required for the safe functioning and operation of medical devices. The technical requirements are such that only a Manufacturer or highly trained representative (ex. Clinical Engineers or Technicians with technical skill) with the proper tools, parts and software can conduct the necessary maintenance procedures. Although deepens on models, "Teikitenken" is implemented at least once a year.

We can see the equipments (ex.MRI) of the high rate but there are the low rate equipments like Potable X-ray and Contract media Injectors

The AMDD`s position on this critical issue is as follows:

- 1) There is a need for greater awareness of this medical safety issue and actions need to be taken to resolve the lack of compliance with the Medical Law.
- 2) Hospitals should be encouraged to utilize their staff and systems to assure daily maintenance and inspection of devices, and request manufacturers to conduct inspection and maintenance that is beyond their ability.
- 3) Government incentives should be made available for compliant hospitals.

## Status of Maintenance

## ◆ Situations of maintenance services

Medical Device	Having maintenance contract with makers (%)	Maintenance by makers (%)	Maintenance by hospital internally(%)	No maintenance (%)	No answer (%)
X ray	16.2	16.4	25.8	30.4	11.2
Auto Contrast injection	16.8	15.2	14.7	35.5	17.7
X ray for surgery	20.4	16.4	18.2	29.8	15.3
X ray for breast	47.9	17.1	13.0	13.7	8.3
X ray for vascular	75.3	8.4	3.4	5.6	7.2
CT	89.2	3.1	0.9	2.9	3.8
MRI	91.5	2.9	0.3	2.4	2.9

Reference: JIRA 8<sup>th</sup> research paper**Regarding to HAI**

Upgrading of quality in healthcare, mitigating avoidable accidents and injuries, and higher efficiency in medical expenses are three targets that can be achieved by aiming at reducing unpredictable accidents, injuries, and predictable infection risk, and by arranging comprehensive guidelines, laws, and regulations for improving safety for patients as well as medical professionals. The World Health Organization (WHO) has specified healthcare-associated infection (HAI) as a major cause of preventable infection/death. A vast amount of medical expenses are consumed in responding to avoidable healthcare-associated infections. Reinforced safety measures and countermeasures for infections will enable drastic reductions in medical expenses.

Medical professionals' safety is a critical issue for their families, workplaces, communities, industries and the nation, as well as themselves. To prevent foreseeable accidents, it is essential to take preventive measures in a comprehensive and systematic manner while involving all parties concerned, including the government, employers, and employees (For further details see References).

# Reference

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical device industry group, based in Washington D.C., U.S.A. It has in excess of 1,900 member companies, including branch offices and business divisions. The AMDD maintains a close cooperative relationship with AdvaMed, since most of the parent companies of the AMDD's member companies belong to AdvaMed.

AdvaMed URL: <http://www.advamed.org/memberportal>

AMDD submitted proposals made by the medical device industry for the development of the New Growth Strategy "Healthy nation strategy through life innovation (innovation in the medical and nursing care sectors)" together with JFMDA and EBC on April 26. These proposals were presented on the basis of three points: 1) review systems for the launch of R&D, 2) review systems for more rapid approvals, and 3) evaluation of innovations.

Web link: [http://www.amdd.jp/pdf/activities/recommen/report100514\\_1.pdf](http://www.amdd.jp/pdf/activities/recommen/report100514_1.pdf)

AMDD submitted co-announcement with JACRI and EBC regarding to review system, necessity to make guideline of clinical performance testing as well as necessity to build new Shonin review standards and rules for Companion IVDs.

Web link: <http://www.amdd.jp/pdf/activities/recommen/report100810.pdf>

The AMDD HAI / Safety Working Group produced the Framework Agreement which contains four sections (Needle stick and Sharp Object Injuries; Reuse of Single-Use Disposable Devices; Infection Prevention Devices; Infection Detection / IVD) targeting the implementation of enhanced safety and infection prevention and control measures in the healthcare setting.

Web link: <http://www.amdd.jp/pdf/activities/recommen/report101012.pdf>

**米国医療機器・IVD工業会**

〒160-0023 東京都新宿区西新宿1-14-11 日廣ビル4F Phone: 03-3343-9164 Fax: 03-3343-9206 URL: [www.amdd.jp](http://www.amdd.jp)

**American Medical Devices and Diagnostics Manufacturers' Association**

Nikko Bldg. 4F, 1-14-11 Nishi Shinjuku, Shinjuku-ku, Tokyo 160-0023 Phone: 03-3343-9164 Fax: 03-3343-9206 URL: [www.amdd.jp](http://www.amdd.jp)