



ISPOR 8th Asia Pacific Conference Issue Panel 21: A New “Challenge Application” Rule – A promising star or mare’s-nest?

11 September 2018

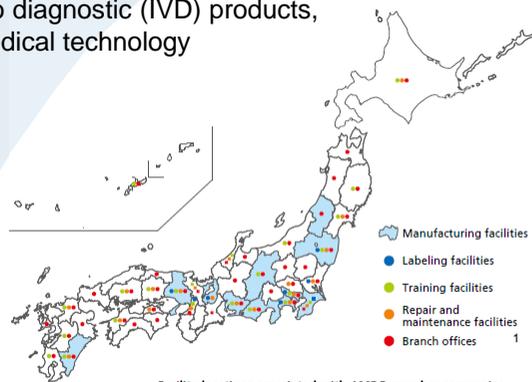
Kosuke Kato
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American Medical Devices and Diagnostics Manufacturer’s Association
(AMDD)

一般社団法人 米国医療機器・IVD工業会
American Medical Devices and Diagnostics Manufacturers’ Association

About AMDD

- The American Medical Devices and Diagnostics Manufacturers’ Association (AMDD)
- Established on April 1, 2009
- Comprised of approximately 60 Japanese companies with headquarters primarily in the U.S. that provide medical devices, in-vitro diagnostic (IVD) products, and other advanced medical technology



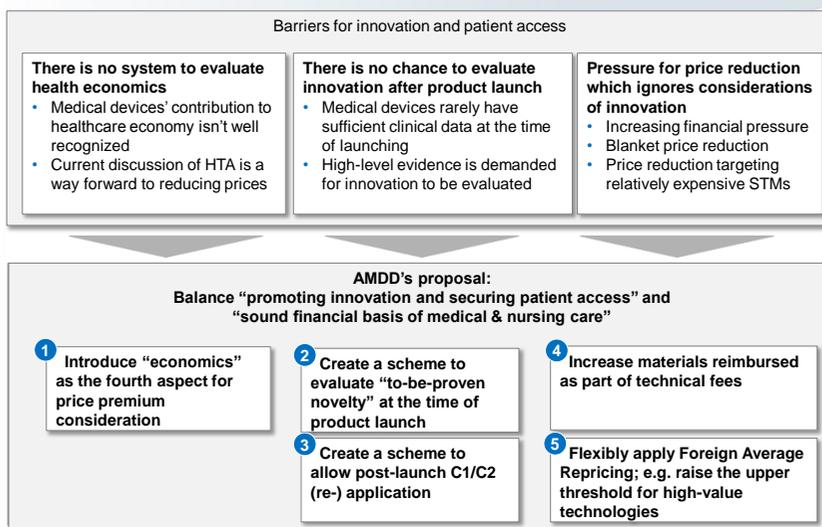
AMDD's proposal on Value-Based Health Care

- In February 2017, AMDD announced the proposal for ensuring access to advanced medical devices and promoting sound financial management of medical insurers - constructing a reimbursement system for medical devices based on Value-Based Health Care
- It aims;
 - to create a reimbursement system that reflects the value of innovation in prices of medical devices
 - to create a resource investment framework that focuses on high-value medical devices and innovation, with the goal of “promoting innovation and securing patient access” and “sound financial basis of medical and nursing care”



AMDD's proposal on Value-Based Health Care

(As of February 2017)



AMDD's proposal on Value-Based Health Care : Balance “innovation & patient access” and “financial efficiency”

Rapidly introduce innovation to enable patient access to care

- 1 Introduce “economics” as the fourth aspect for price premium consideration
- 2 Create a scheme to evaluate “to-be-proven novelty” at the time of product launch
- 3 Create a scheme to allow post-launch C1/C2 (re-) application

Improve financial efficiency of medical & nursing care

- 4 Increase materials reimbursed as part of technical fees
- 5 Flexibly apply Foreign Average Repricing; e.g. raise the upper threshold for high-value technologies

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Improve financial efficiency of medical & nursing care

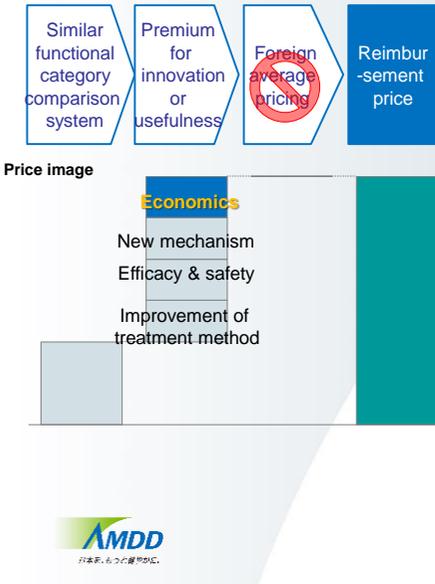
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1 Introduce “economics” as the fourth aspect for price premium consideration

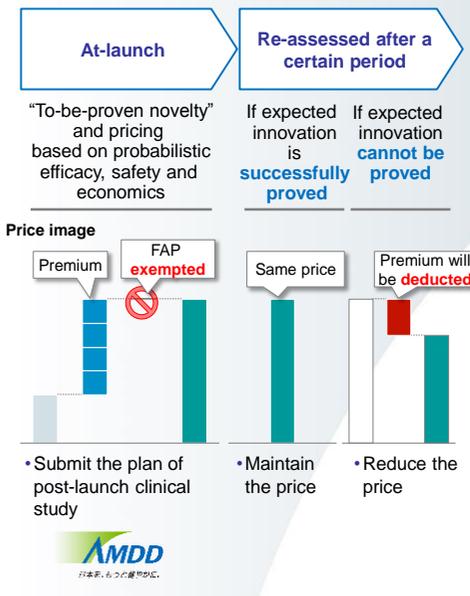


- Currently, premium for innovation or usefulness are evaluated from three aspects; "new mechanisms", "efficacy and safety" and "improvement of treatment methods".
- **We propose to add “economics”** as the fourth aspect for price premium consideration.
- “Economics” should not be based only on the medical costs but also the savings in nursing care costs or burden for caregivers.
- When evaluated from an **economic perspective** based on the Japanese healthcare market, the device should be **exempted from the foreign average adjustment**

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2 Create a scheme to evaluate “to-be-proven novelty” at the time of product launch

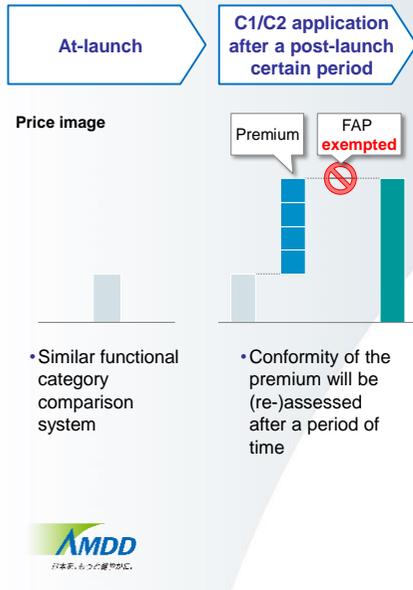


- We propose to create a scheme to evaluate “**to-be-proven novelty**”
- The devices will be re-assessed after a certain period of time, based on the outcomes from post-launch clinical data obtained through public database, etc.
- If the outcome of post-launch clinical data will not meet the initially **expected efficacy, safety or economics**, the **price premium added** due to the “to-be-proven novelty” **will be taken away**.
- When evaluated from an **economic perspective** based on the Japanese healthcare market, the device should be **exempted from the foreign average adjustment**

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3 Create a scheme to allow post-launch C1/C2 (re-) application



- If the post-launch clinical data will prove the premium aspects (efficacy, safety, economics etc.) that weren't evaluated at the time of reimbursement listing, the company will be able to apply for price premium consideration
- When evaluated from an **economic perspective** based on the Japanese healthcare market, the device should be **exempted from the foreign average adjustment**

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AMDD's proposal on Value-Based Health Care : Balance "innovation & patient access" and "financial efficiency"

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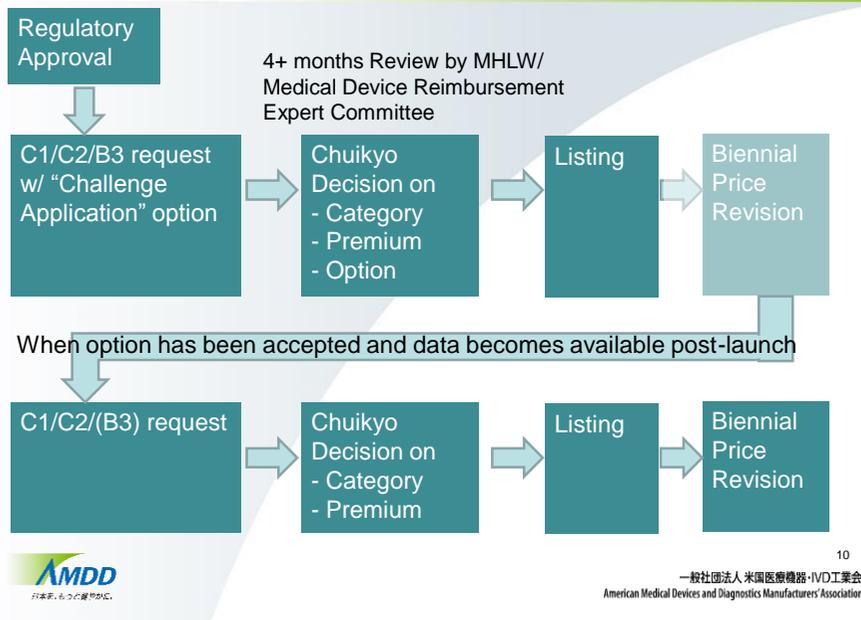
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Reflected in New "Challenge Application" Rule

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Perceived process of “Challenge Application”



Industry’s evaluation of “Challenge Application”

- We welcome the creation of a new option aligned with the AMDD proposal
- While we are not fully satisfied with the result that “to-be-proven novelty” has not been realized, we may need to accept it
 - Patient access to innovation is secured as the minimum reimbursement can be provided (i.e. reimbursement without premium/ “Advanced Medical Care” scheme where all cares other than the “advance medical technology” be reimbursed)
- We agree to bear the cost of data collection, considering the nature “Challenge Application” aiming to obtain only premium portion

Industry's concerns about "Challenge Application"

- Whether will the price premium be really given?
 - Current scheme does not require setting a target for outcome beforehand
 - It could be a risk manufacturers because MHLW might require a higher target outcome than expected
 - However, it could also give manufacturers the opportunities to claim price increase when unexpected outcome will show the value of technology
- Would "Challenge Application" pathway increase the denial of price premium at initial application?
 - Target of efficacy and effectiveness at-launch might be raised by providing a potential remedy

Conclusion on "Challenge Application"

- Industry welcomes this new rule as a good step
- However, some concerns exist as described above



Would like to:

- ✓ Hear the observations regarding the current "Challenge Application"
- ✓ Discuss about the right course of value-based healthcare in Japan including "Challenge Application"

THANK YOU



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