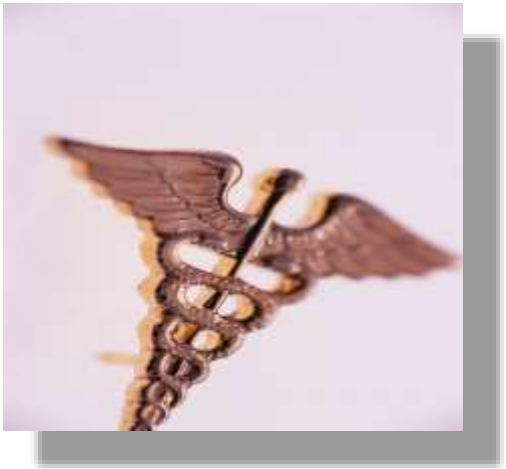
The Summary of Medical Device Reimbursement (2016 Japan)

JFMDA
The Japan Federation of Medical Devices Associations



Jun 23,2016
Toshiei Mizutani
Chair, Medical Material Reimbursement Committee, JFMDA

診療報酬改定の国民生活への影響

医療費約43.0兆円

（2015（H27）年度予算ベース）

診療報酬を▲１％適正化した場合

約▲4,300億円の医療費の抑制

- 国民負担の軽減（税金、保険料、患者負担）
- 医療機関等の収入減

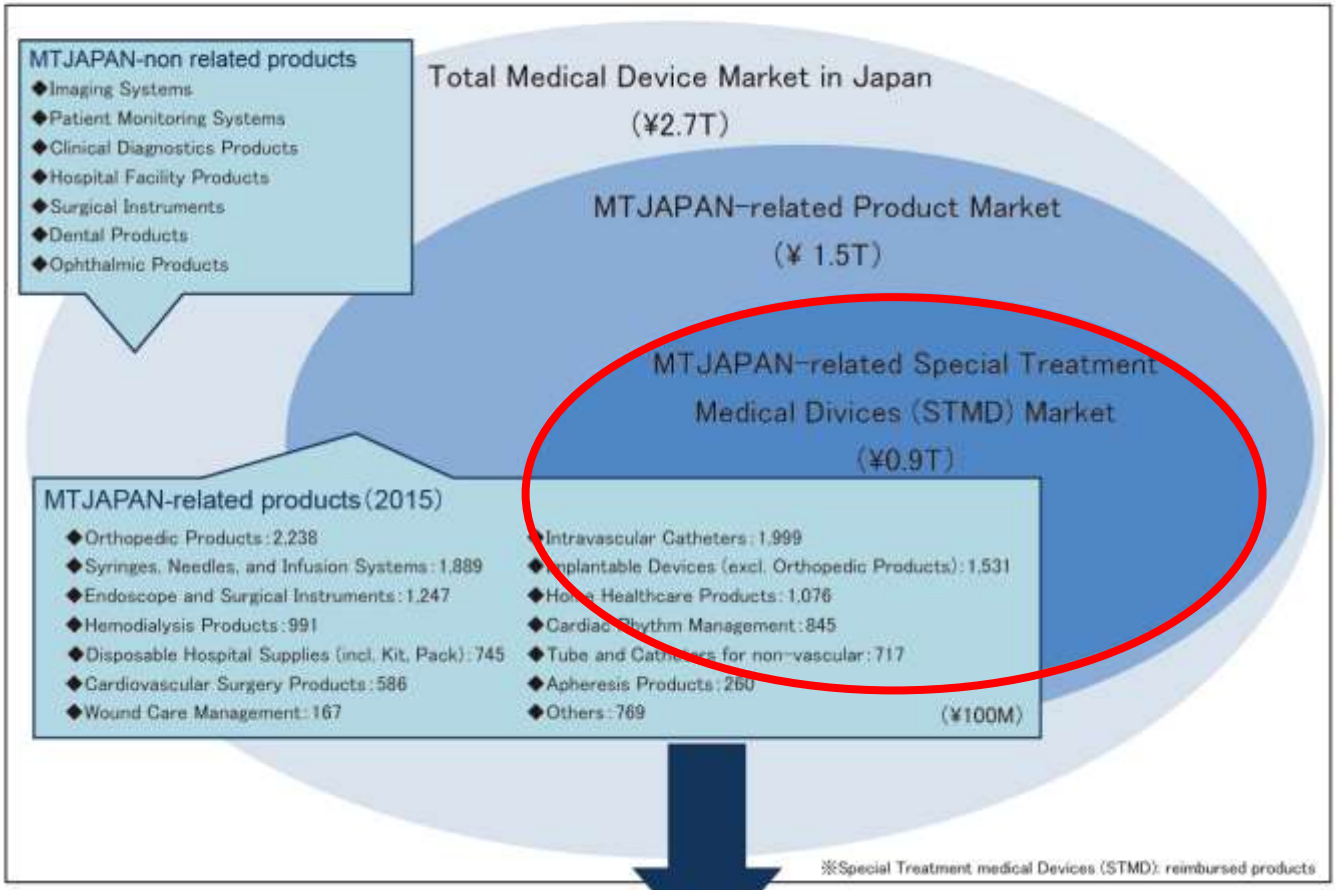
※　2015（H27）年度予算ベースの医療費を公表されている最新の内訳で按分

（出所）費用構成比：厚生労働省保険局資料、財源構成比：厚生労働省「平成24年度国民医療費の概況」

財政制度等審議会　財政制度分科会資料　H27.10.30より

The status quo of MTJAPAN

- The total volume of domestic sales amount of MTJAPAN-related product is about 1.5 trillion yen.
  This accounts for 56% of the medical device market in Japan.



The medical device price (reimbursable) standard establishes the prices that are paid to medical institutions or pharmacies for the reimbursement of special treatment medical device(STM)

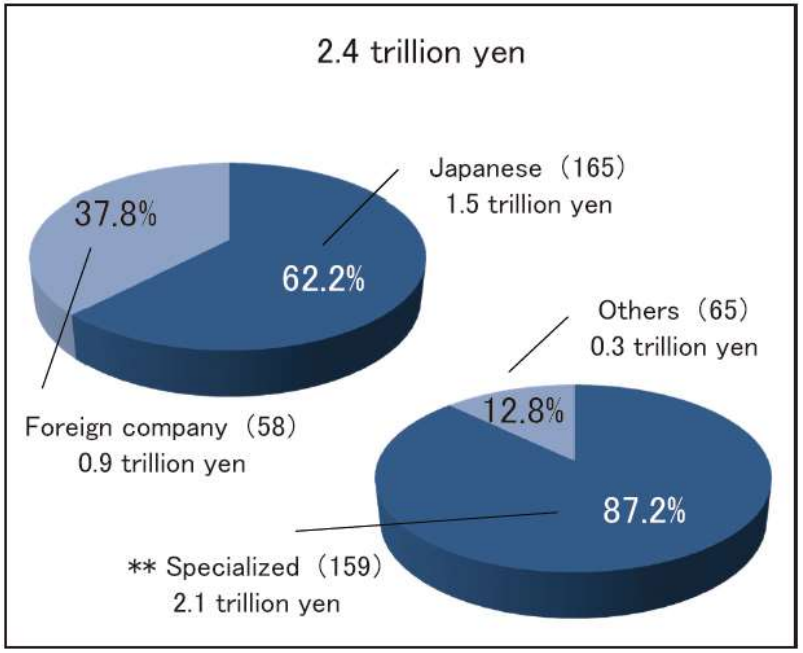
国内医療機器市場:平成25年薬事工業生産動態年報より
MTJAPAN範疇製品:2015年度MTJAPAN調査より

Snapshot 1

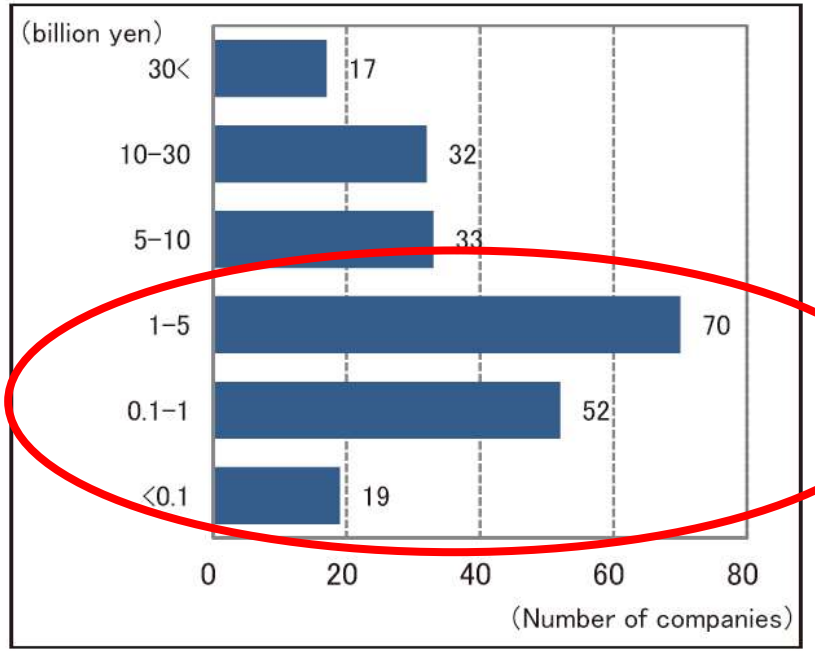
Sales of medical devices in Japan

- Total sales of medical devices (223 companies) including OEM product and parts, are approximately 2.4 trillion yen.
- The ratio of Japanese to foreign companies is 6:4.
- 141 companies out of 223 (63%), have sales of less than 5 billion yen.

Breakdown of sales by company classification



Number of companies by revenue



* ( ): Number of companies

** More than 50% of sales generated from medical devices

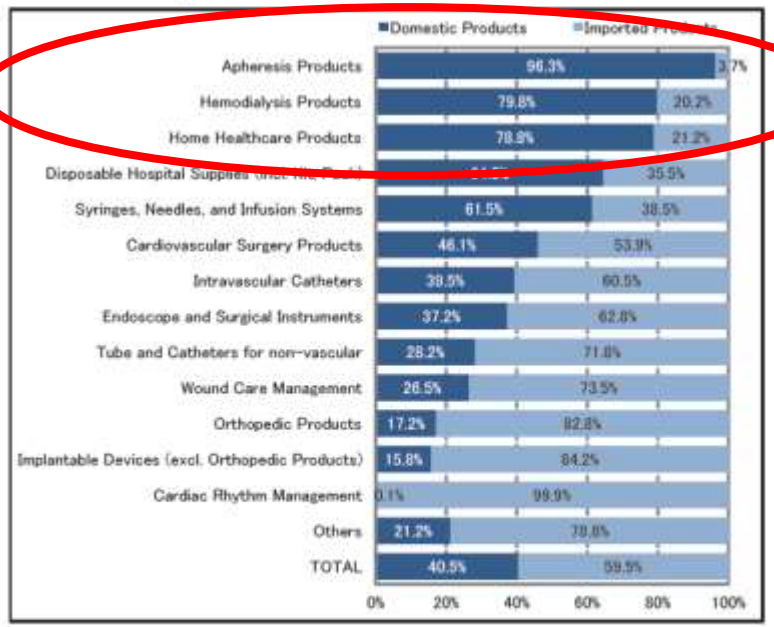
MTJAPAN DATA BOOK 2015

Snapshot 5

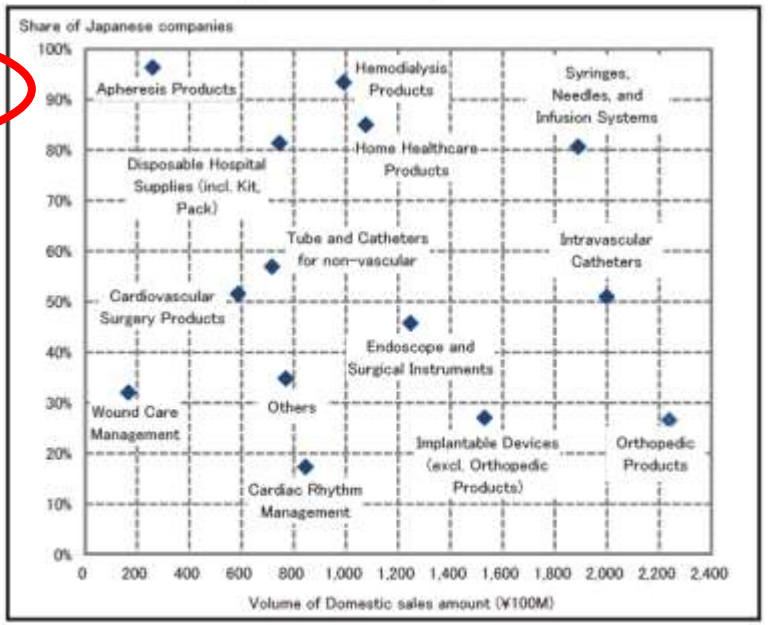
Share of imports and presence of Japanese companies

- Imported products account for 59.5% of total domestic sales amount. “Cardiac Rhythm Management”(99.9%), “Implantable Devices”(84.2%), and “Orthopedic Products” (82.8%) have high shares of imported products.
- Japanese companies have significant presence in “Apheresis Products”, “Hemodialysis Products”, and “Home Healthcare Products” segments.

Share of imports within total domestic sales amount



Presence of Japanese companies



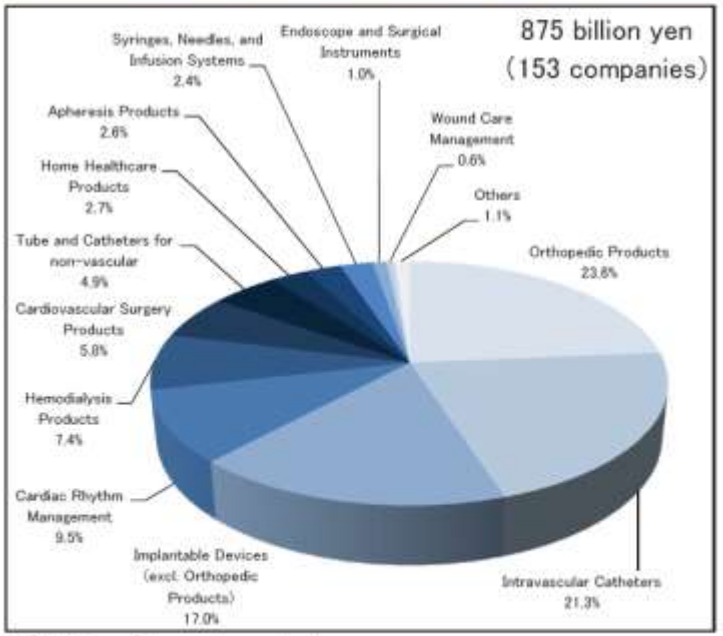
The medical device price (reimbursable) standard establishes the prices that are paid To Medical institutions or pharmacies for the Reimbursement of special treatment medical device(STM)

Snapshot 4

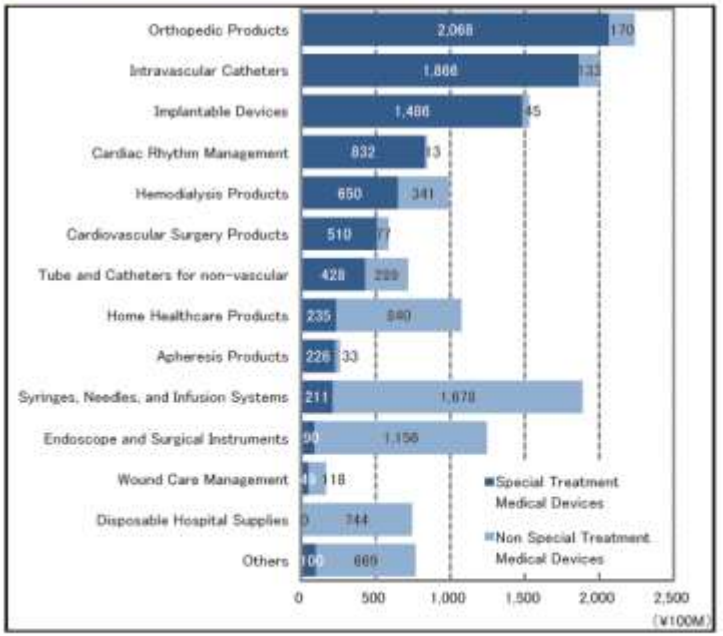
Domestic sales amount of MTJAPAN-related Special Treatment Medical Devices (STMD)

- The total volume of domestic sales amount of MTJAPAN-related Special Treatment Medical Devices is 875 billion yen (58.1% of total domestic sales amount).
- The largest segment is "Orthopedic Products"(206 billion yen) with 64 companies, followed by "Intravascular Catheters", and "Implantable Devices".

Domestic sales amount of STMD by segment (%)



Domestic sales amount of STMD by segment (volume)



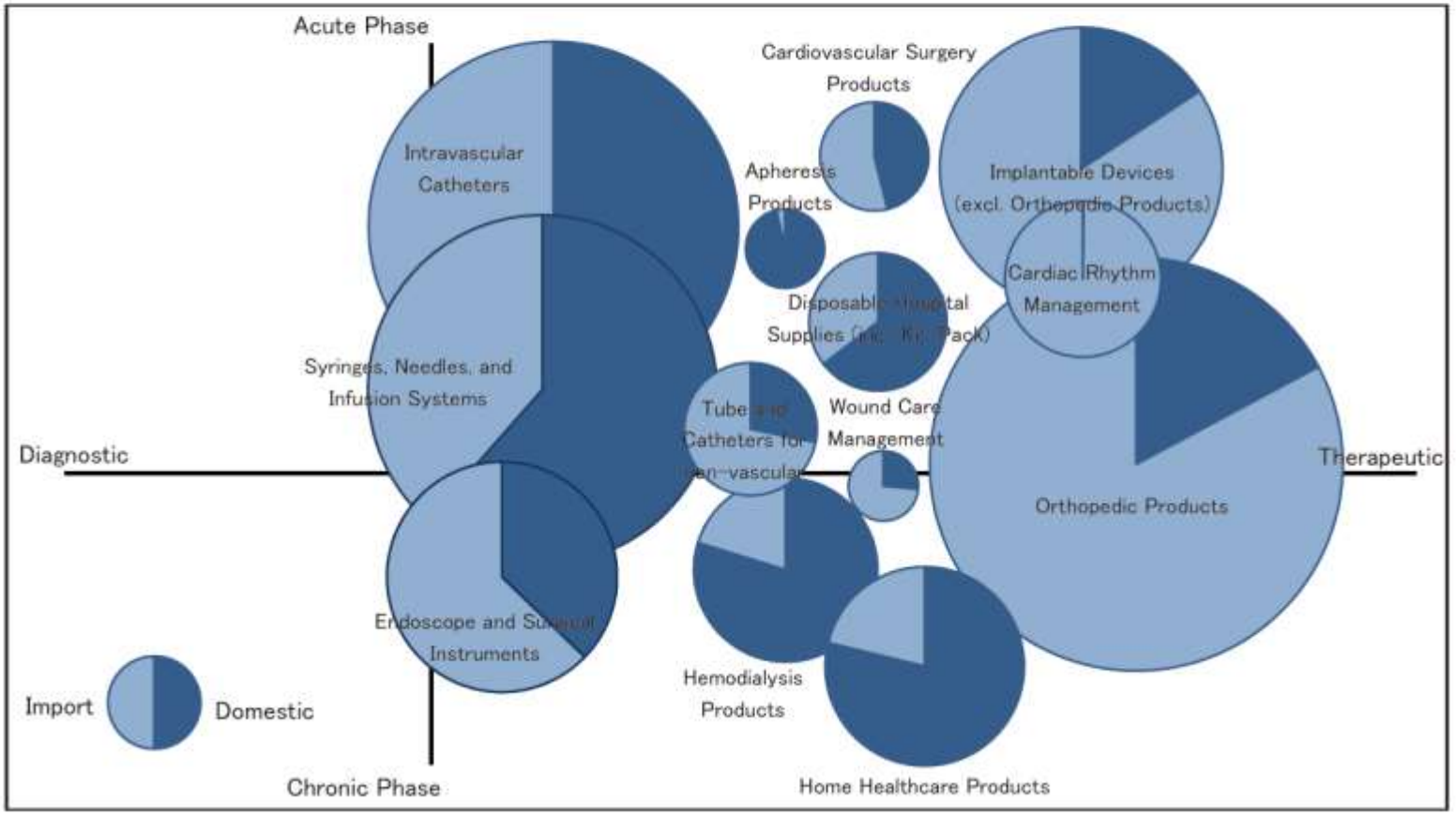
* STMD: reimbursed products

MTJAPAN DATA BOOK 2015

Snapshot 7

Segment positions by product classifications and share of imports in each segment

- MTJAPAN-related products are mainly therapeutic products. Import share is higher in the acute phase.



1. What are Special Treatment Medical Devices (STM) ?

Evaluation of medical equipment for compensation (1)

There are three categories of medical device

A1 : Comprehensive : The technical fee comprises the cost of medical device.
(e.g., sutures, gauzes)

A2 : Specifically comprehensive : Items that are evaluated comprehensively in specific categories
(e.g., PET, CT, MRI)

B : Individual evaluation : = *Special Treatment Medical Device (STM : reimbursable medical device)*
Device prices that are individually determined and evaluated (e.g., pacemakers, artificial joints)

C1 : New-function products : Products that need a new function classification and have already been evaluated for technical fee (e.g., drug eluting coronary stents)

C2 : New-function/technology products : Products that need a new function classification and have not yet been evaluated for technical fee (e.g., implantable artificial hearts)

F: Materials and products not suitable for reimbursement from health insurance

Evaluation of medical equipment for compensation (2)

Medical equipment
(as defined in the Pharmaceutical Affairs Law)

A2
Specifically comprehensive

Medical machine
(in the narrow sense of the term, such as PET, CT, MRI)

Medical device
(e.g., catheters, heart valve)

C2
(New-function/technical fee)

B Individual evaluation
= **Special treatment medical device**

A1
Comprehensive

C1
New-function

2. The Standard System of STM Reimbursement

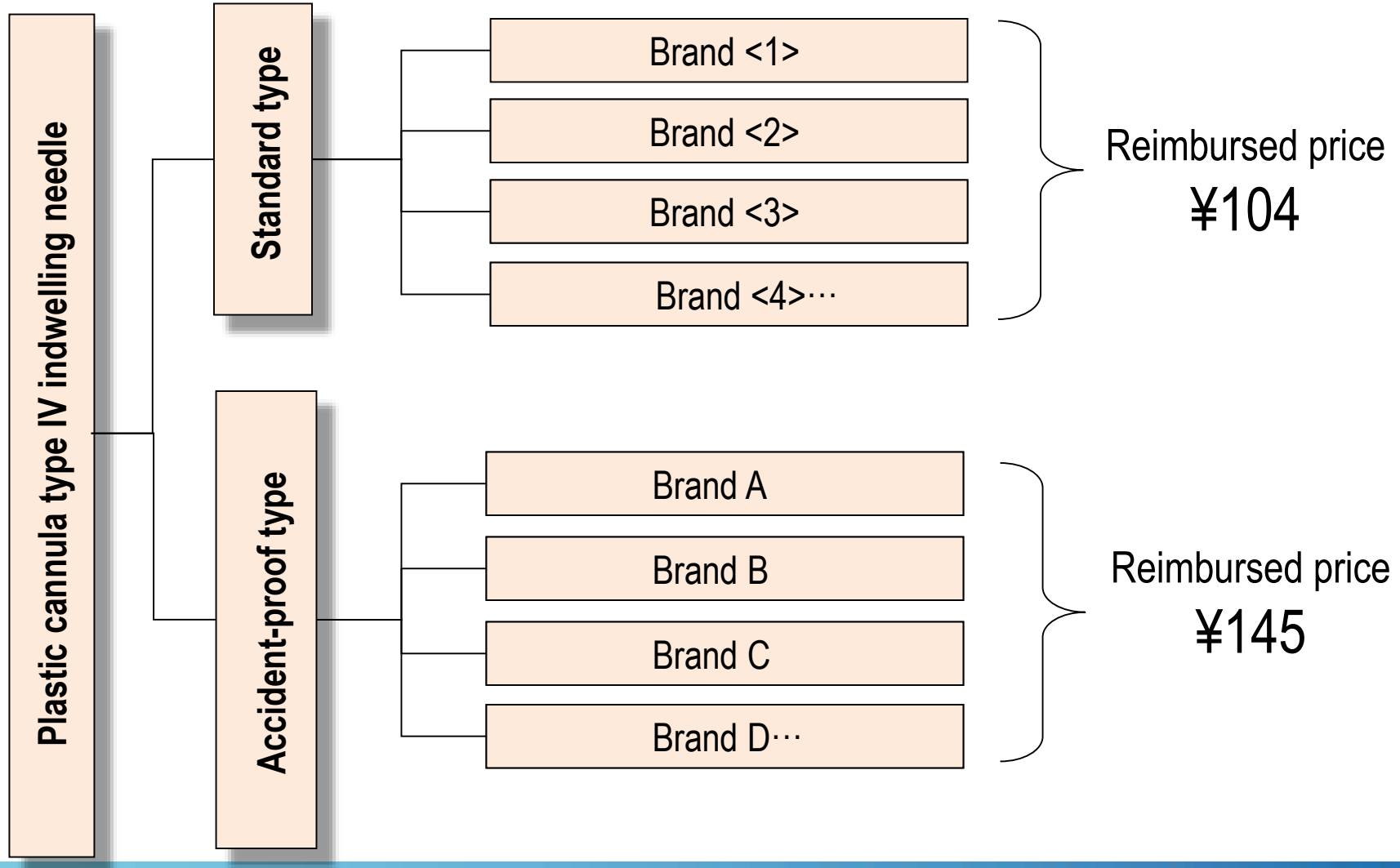
Summary

<1> The medical device price (reimbursable) standard establishes the prices that are paid to medical institutions or pharmacies for the reimbursement of special treatment medical device (STM)

<2> The MHLW considers the price of STM which have a similarity with respect to structure, purpose of use and indications and are classified into the same specific functional category of medical device, and then announces the price of the STM device.

<3> The MHLW periodically revised prices that are established by the Medical Device Price Standard System based on the actual purchase prices (result of the medical device price survey, once every two years) paid by medical institutions or pharmacies.

Example of Functional Category

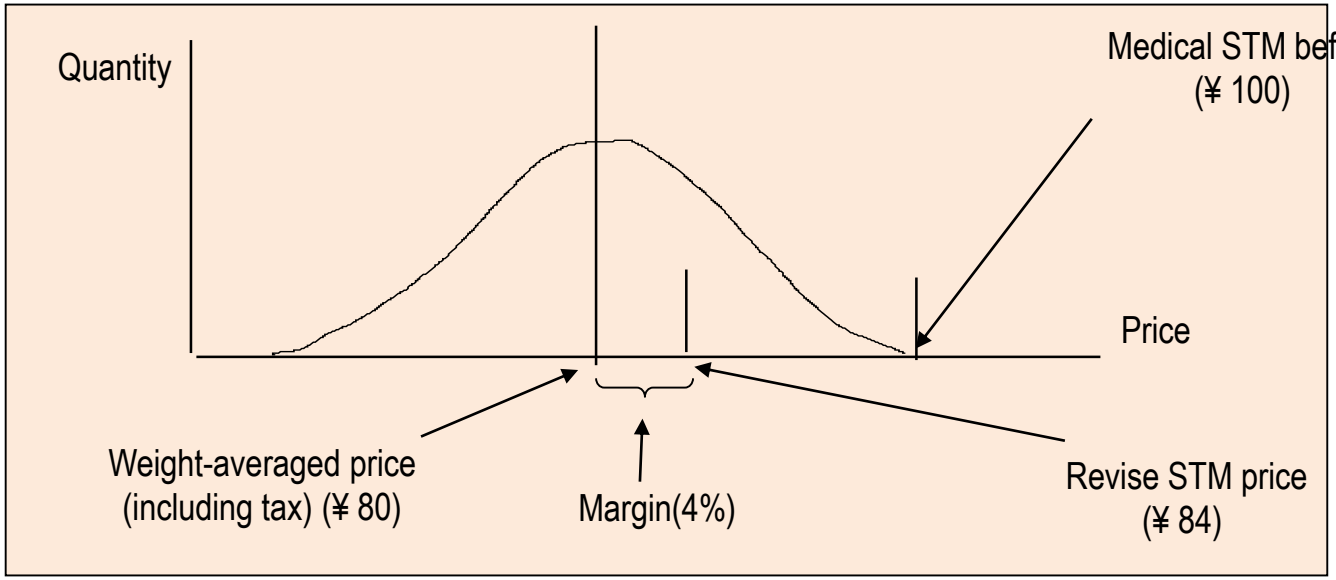


3. Reimbursement rules for existing STM

Basic rule of existing STM price revise

○ Weight-averaged market price plus margin

The weight-averaged market price plus margin is the sum total of the weight-averaged market price plus consumption tax and a fixed margin (4.0%). The STM price is revised once every two years based on STM price survey.



Revise STM price = [Weight-averaged purchase price paid by a medical institution (market price excluding tax)] × 1 + Consumption tax (including local consumption tax) + Margin

Exceptional rule of existing STM (Foreign Reference Price)

○ Price reduction

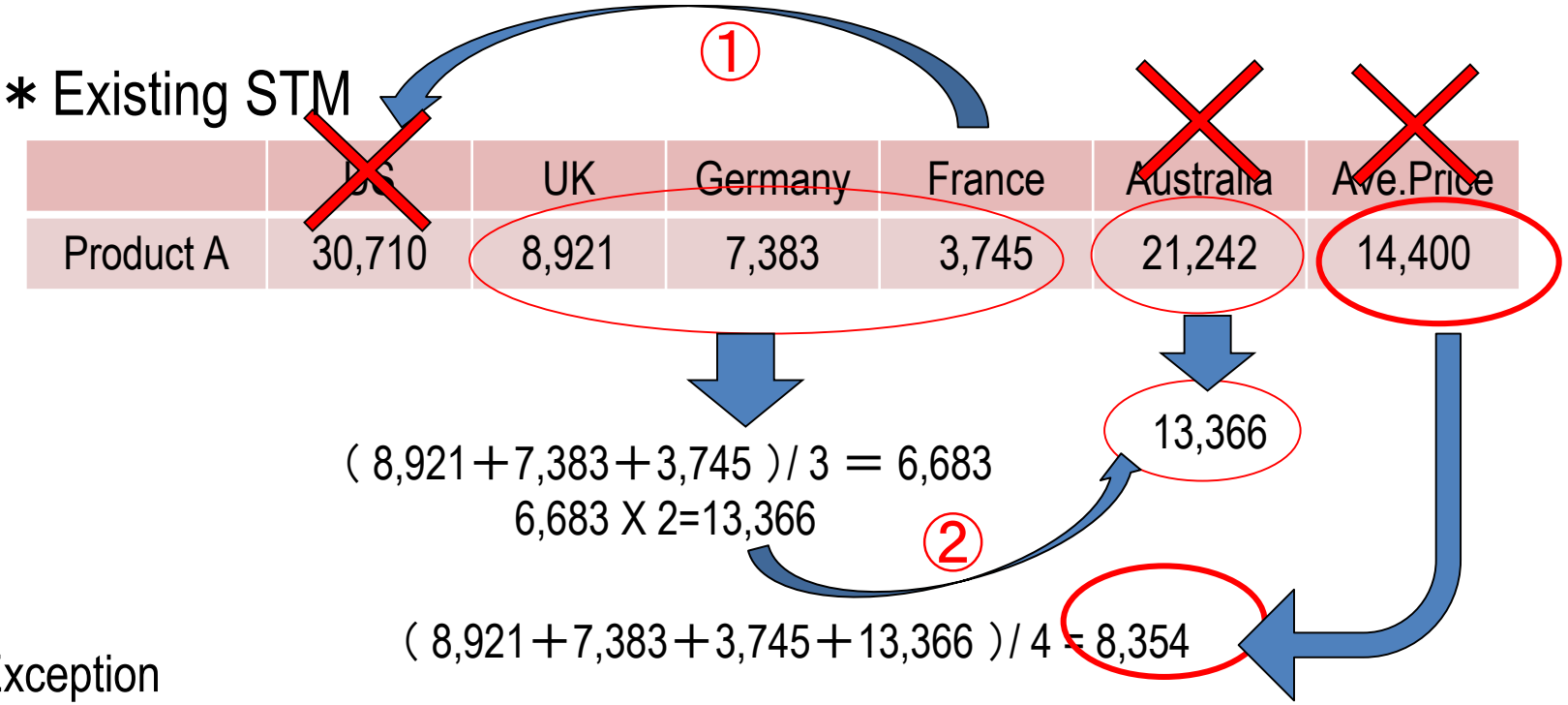
(1) The price will be reduce to 1.3 times the average overseas price.
(ie U.K., U.S., Germany, France, Australia)
or

(2) if the domestic market price is more than 1.3 times higher than the average overseas price * and the rate of decrease from the standard device price revised since the last price revision is within 15%, the price will be reduced using the following formula (bat reduced by no more than 25%).

$$\text{Revise price} = \text{device price before revision} \times \frac{\text{Average overseas price of an existing product} \times 1.3}{\text{Weight-average market price of a brand in a particular functional category}}$$

＊Foreign reference price adjustment (Exception)

＊Existing STM



＊Exception

①If the highest price is 3 times higher than the lowest price, the average price will be recalculated excluding the highest price.

②Thereafter, if the country with the highest price is still more than double the average price of the 3 countries price with the lowest price, the that price will be reduced to two times the average.

4. Rule for calculation of a New STM price

Basic rules of New STM (As of April 2016)

○ Similar functional category comparison system

The prices of existing STM that are considered to have the highest similarity with respect to structure, purpose of clinical use and indications will be the benchmarks for a new device of the same functional category.

Premiums* will be paid for the unique functions that each device features.

*Premiums

- Epochal function premium 50-100%
- Utility premium 5-30%
- Improvement premium 1-20%
  (Be highly probable 1-10%)
- Orphan device premium (I) 10%
- Orphan device premium (II) 1-5%

Basic Rules (Detail) of New STM

○ Epochal function premium (50-100%)

A newly listed STM of a new function category that meets the following requirements:

A. STM that has a novel function of clinical utility.

B. STM has been objectively shown to have higher utility or safety than listed STM of a similar function category.

C. A newly listed STM that has been objectively shown to improve the method of treatment for the target disease or wound.

○ Utility premium (5-30%)

A newly listed STM of a new function category that meets one of the requirements for the epochal function premium

○Improvement premium (1-20%)

(Be highly probable 1-10%)

A newly listed STM of a new function category that meets the following requirements:

A. STM has been objectively shown to structurally have higher safety for healthcare professionals than listed STM of a similar function category.

B. A newly listed STM of a similar function category that has been objectively shown to have less impact on the environment when disposed of after use compared to existing STM.

C. Use of STM has been objectively shown to be a less invasive treatment than of listed STM of a similar function category.

D. STM has been objectively shown that new treatment to infants etc. is made possible by miniaturizing and lightening, though the new treatment was impossible using existing STM that belongs to the similar function category.

+

○ Orphan device premium (I) (10%)

A new listed STM of a new function category that is designated as an orphan drug in accordance with the provisions of Par. 2 of Article 77 of the Pharmaceutical Affairs Law

○ Orphan device premium (II) (1-5%)

A newly listed STM of a new function category that has less target patients than do listed STM of a similar function category

Exceptional rule of New STM

○ Cost accounting system

For STM that do not fall under any similar function category, the sum total of the manufacturing (import) cost, selling and administrative expenses, an operating profit, distribution expense, and general and local consumption taxes shall be the price of STM of a new function category.

Foreign reference price adjustment of New STM

○ Price adjustment

There are two methods of calculations:

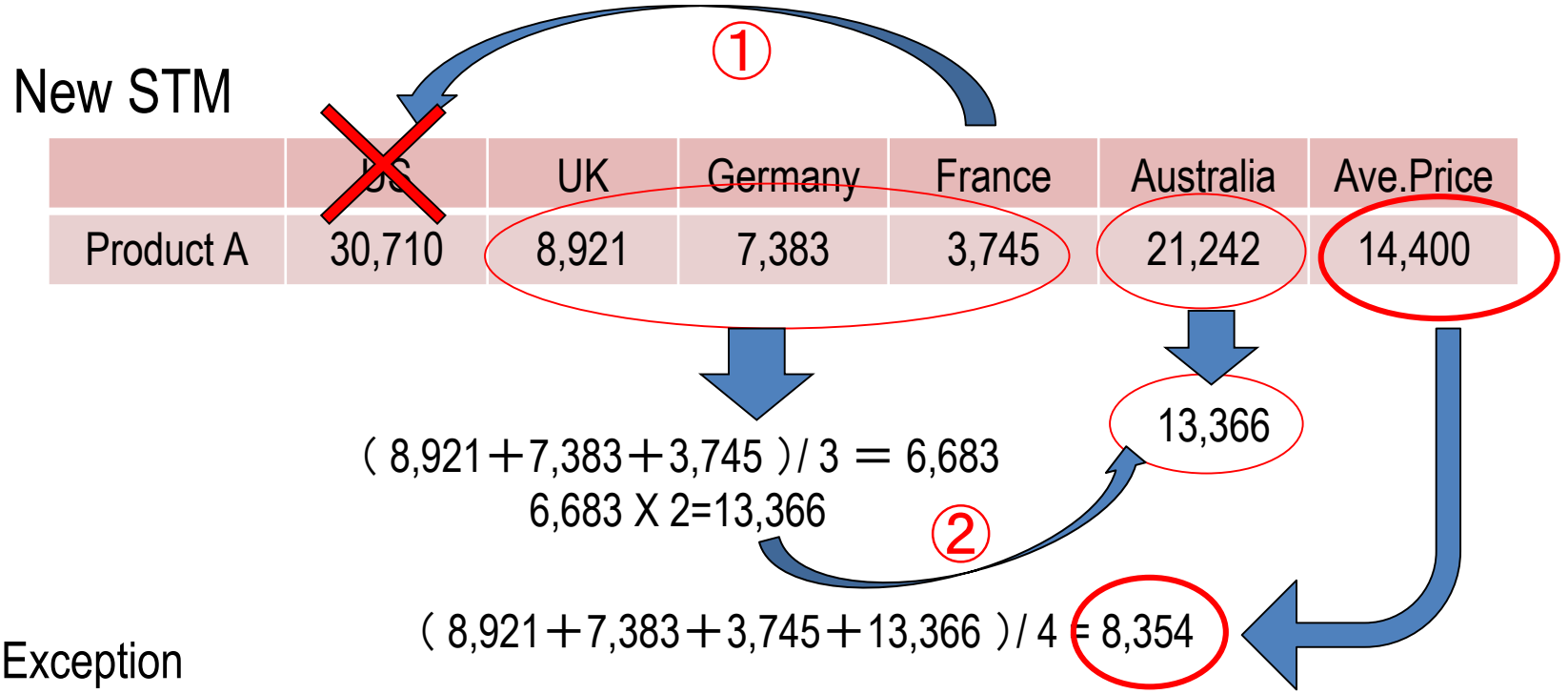
(1) If the new domestic price is more than 1.3 times higher than the average overseas price.

or

(2) If the highest price is 3 times higher than the lowest price, the average price will be recalculated excluding the highest price.
Thereafter, if the country with the highest price is still more than double the average price of the 3 countries price with the lowest price, the that price will be reduced to two times the average.
（As explained earlier on the foreign reference price adjustment slide)

Foreign reference price adjustment (Exception)

New STM



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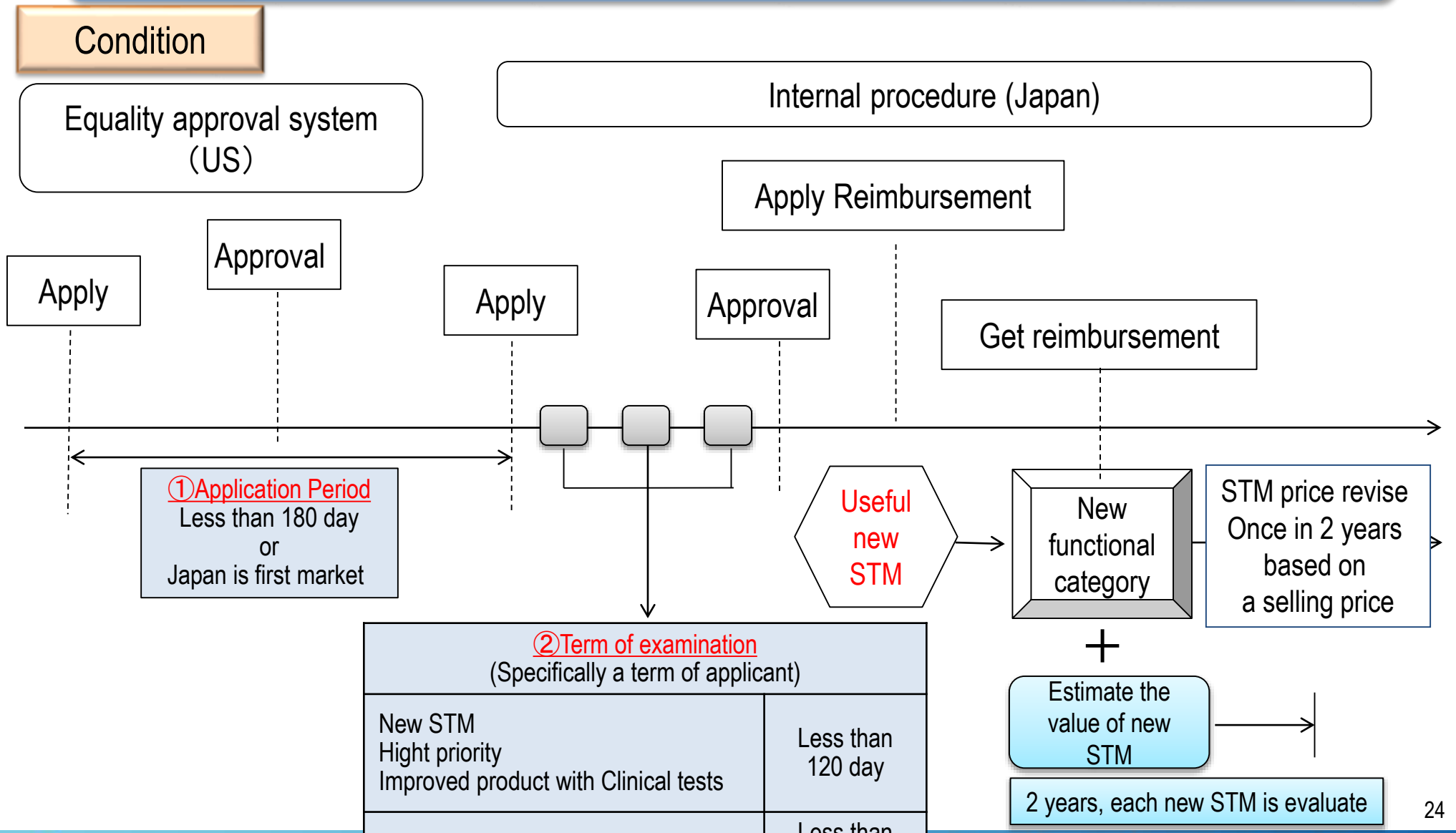
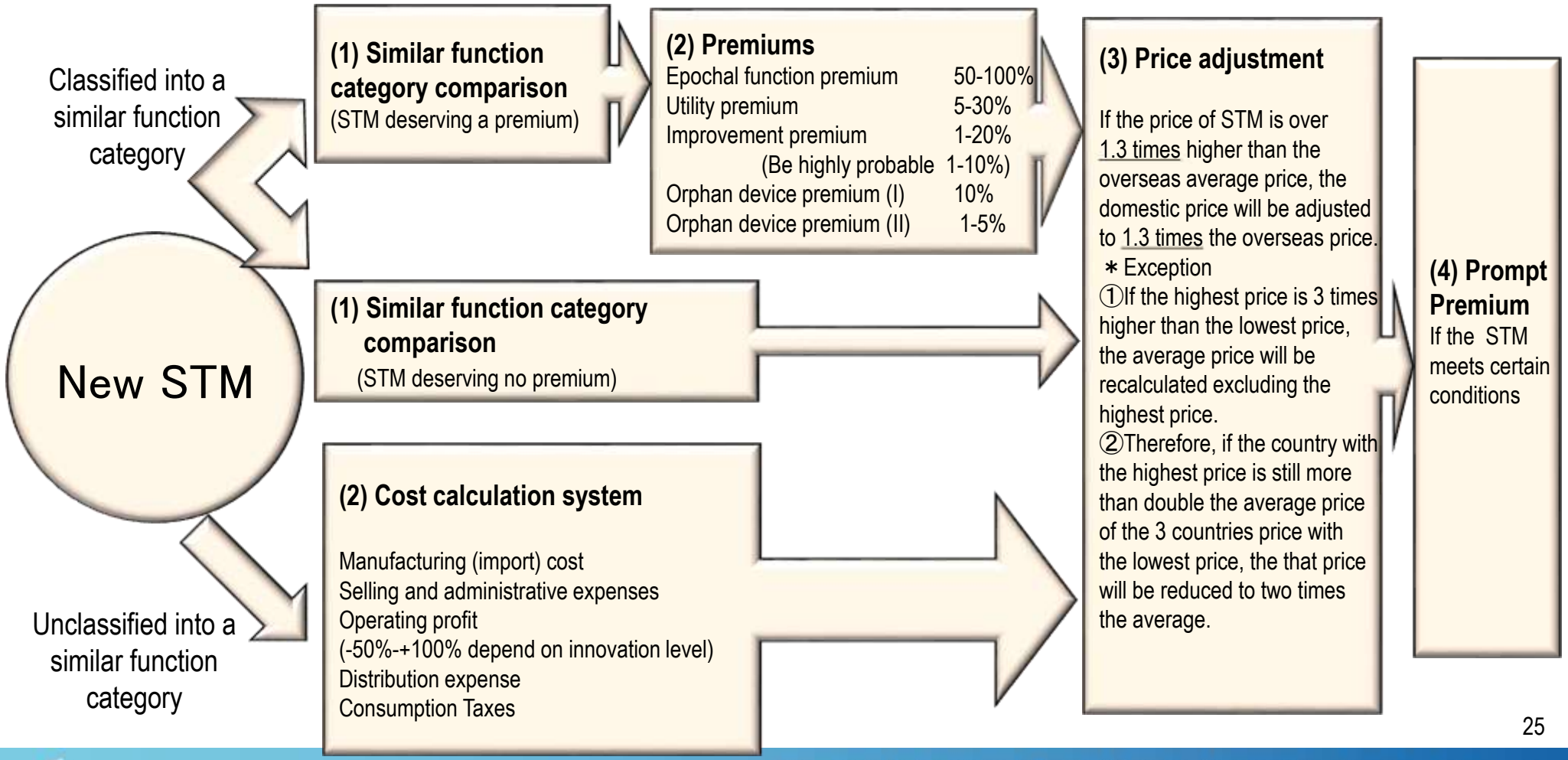
Prompt Premium if New STM meet a condition



Conclusion of New STM (As of April 2016)



5. Procedure for medical device reimbursement

Procedure for medical device reimbursement (As of April 2016)

Submission for a "request for health insurance reimbursement"

<Manufacturers, etc.>

Examination of applications

A1 (Comprehensive)
A2 (Specifically comprehensive)
B (STM : Individual evaluation:)

C1 (New function)
C2 (New function/technical fee

Preparation of a draft decision

Study of the draft decision

< Medical device specialist committee >

Notification of the draft decision

No objection

Objection raised

Interviewing of the applicant

< Medical device specialist committee >

Approval by the Chuikyo

Listing in the NHI Reimbursement

A2 (specifically comprehensive) and B (individual evaluation) are reported to the Chuikyo.

As for desired classification, the application is classified as "non-applicable" or F.

Time-line of Reimbursement

A1 (Comprehensive): 20 days after submission of the application

A2 (Specifically comprehensive)
B (Individual evaluation): First day of the next month for applications submitted by the 10th day of each month

C1 (New function): 4 times a year (March, June, September, December)

C2 (New function/technical fee): 4 times a year (March, June, September, December)

Introduction of Medical Device Reimbursement System in South Korea

1st Japan-Korea Joint Symposium on Medical Products

June 23rd, 2016

Sang-Soo Lee, MBA
Chair, Reimbursement Policy Committee, KMDIA
Corporate Affairs Director, Medtronic Korea Ltd.

KMDIA 사단법인 한국의료기기산업협회
Korea Medical Devices Industry Association

Presenter Information

- Chair, Reimbursement Policy Committee, KMDIA
- Corporate Affairs Director, Medtronic Korea Ltd.
- Chair, Medtronic Asia-Pacific Reimbursement Leadership Council (APRLC)
- Co-chair, AmCham Medical Device Committee
- Board of Director, Korea Association of Health Technology Assessment
- 22 years in medical device industry
  - Medtronic Korea Ltd.
  - Johnson & Johnson Medical Korea

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Korea Medical Devices Industry Association

Healthcare landscape in South Korea

Growth drivers & Challenges

Government /Regulator

- **Continuous reimbursement price cut & market access challenges**
- Healthcare as a growth engine driven by Gov't. esp. R&D support for local
- Movement for lifting legislative barrier for U-Healthcare

Producer /Medical devices

- **Flat market growth (8.4% CAGR, 2014)**
- MNCs dominant(64%, 2013) but fierce competition with local manufactures
- Korean conglomerates trying to enter healthcare market

Provider

- **Continuous dominance by general hospitals incl. tertiary hospitals**
- Poor profitability of hospitals [Big 5 center (EBIT -2%), 2013]

Payer

- **Reimbursement coverage expansion**
  - 62% → 72% (OECD Avg.) esp. 4 major severe diseases
- Continuous growth of private insurance market ($20Bil. 2014)

Patient

- **Fastest growing aging population with increasing chronic diseases**
- Shift purpose of care from treatment to prevention

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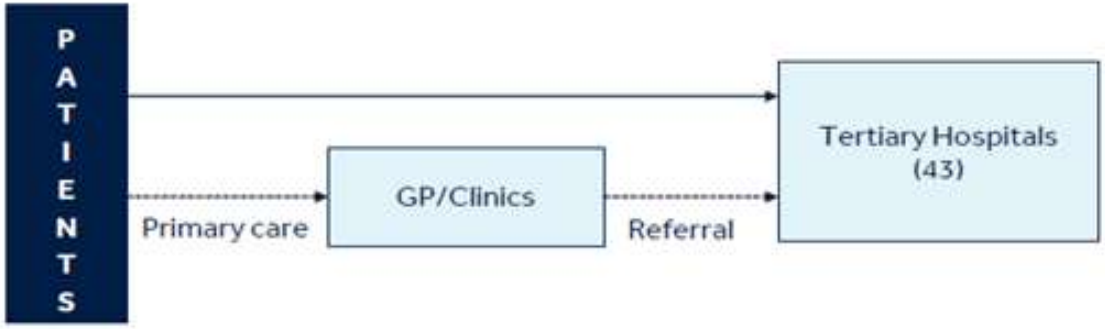
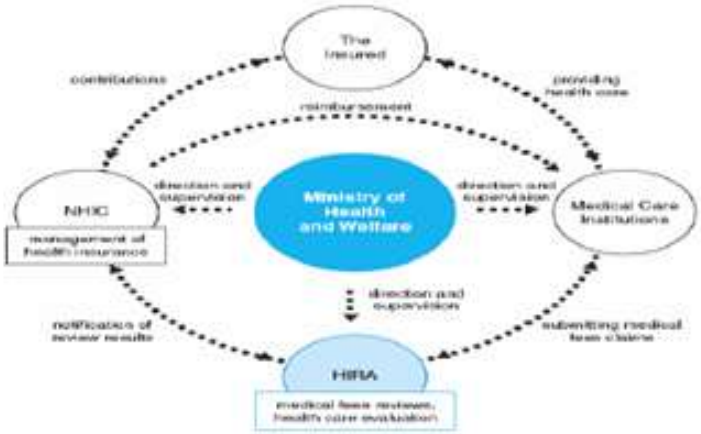
Korea healthcare market

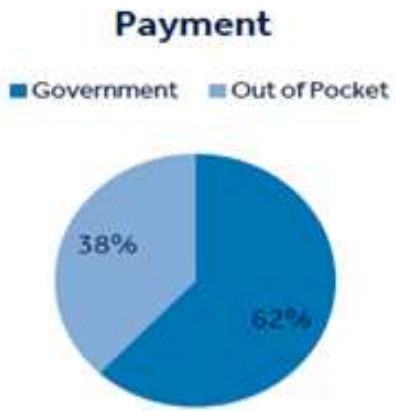
PATIENT PERSPECTIVE



Source: European Observatory on health systems and policies

PAYER PERSPECTIVE





IMPLICATIONS

- Weak referral system
- Easy access to tertiary care
- Rampant medical shopping

IMPLICATIONS

- Pressure on healthcare spending from fastest growing aging population and increasing chronic disease burden
- Movement to introduce remote medical treatment
- Gradual reimbursement coverage expansion from 62% to OECD avg. (72%)

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Korea Healthcare Framework

	Korea	Japan	Australia
Healthcare System	Universal / National Health Insurance (albeit, >90% of hospitals owned by private)	Universal / NHI	Public + Private
# of Payers	**1**	6	42 : Public(8) + Private(34)
Healthcare Spending as % of GDP (2011)	7%	10%	9%
Healthcare Expenditure per Capita (2011)	$1,604	$4,315	$4,558
Device Expenditure	4% (2013)	2% (2013)	3% (2011)
Payment System	• Integrated physician and hospital fee : fee-for-service • Device fee : fee-for-service • DRG for commodity therapy (7 disease groups)	• Integrated physician and hospital fee : fee-for-service • Device fee : fee-for-service • Introduction of DRG is under trial for limited therapies	**Public** • DRG case payment (covers hospital, physician and device fees) **Private** • Hospital fee : DRG • Physician fee : fee-for-service • Device fee : fee-for-service (Prostheses List)
Copayment Rates	**5, 10, 20, 30, 50, 80, 100%**	0~30%	• Hospitals : 5% • Medical services : 12%
Healthcare Funding : Public / Non-public including out-of-pocket (2011)	**55% / 45%**	82% / 18%	68% / 32%
HTA	**In place**	Not yet in place	Applicable in private

Overview of medical device reimbursement

- Fee-For-Service scheme
- Functional category system
- Single reimbursement price for the same functional category
- Reimbursement submission is required within 30 days after Ministry of Food Drug Safety (MFDS, former KFDA) regulatory approval
- Clinical evidences are required
- Economic evidence is not mandatory but preferred

Lee SS, Salole E. Medical Device Reimbursement Coverage and Pricing Rules in Korea: Current Practice and Issues with Access to Innovation. Value in Health 17 (2014) 476-481

Reimbursement pricing mechanism – Comparison with Japan

Categories	Korea	Japan	Example
Reimbursed	• Comparing the product with those already listed and in the same "functional category"	B	Pacemaker, ICD, CRT-P/D
	• New device considered superior, reimbursement is applied Track 1, 2 criteria and a new functional category is created	C1/C2	MRI compatible pacemaker
Funded under the procedure fee	• Consumables and included in the procedure fee	A1/A2	Consumables (Syringe, etc.)
Unreimbursed	• Cosmetic, expensive or not clinically essential • Less clear guidance about which characteristics determine their out-of-pocket classification and ineligibility for reimbursement	F	Artificial cervical disc

Lee SS, Salole E. Value in Health 17 (2014) 476-481

Reimbursement decision process

Table 1 – Medical device reimbursement approval process.

Step	Process	Process description
1	Reimbursement application must be submitted within 30 d after Ministry of Food and Drug Safety (MFDS) approval	Application to the Ministry of Health and Welfare (MOHW) or Health Insurance Review and Assessment Services (HIRA). Manufacturers, medical institutions, and medical societies may submit applications.
2	HIRA review	Review of appropriateness of coverage and reimbursement price. Consideration of eligibility for reimbursement and estimation of budget impact. Review of comparable devices already listed. Comparison of cost-effectiveness with currently listed devices (by reviewing the application, the literature, seeking medical society opinion, etc.). Collation of internal/external expert opinion.
3	Medical Device Expert Evaluation Committee (MDEEC) review	Recommendation on reimbursement coverage and price made within 100 d of application. Consideration of economic feasibility (i.e., substitutability and cost-effectiveness) and appropriateness for funding.
4	Health Insurance Policy Deliberation Committee (MOHW)	Confirmation of decision about reimbursement coverage and price.
5	Publication of reimbursement approval notice	Approval notice published on the MOHW Web site within 150 d of application.

Lee SS, Salole E. Value in Health 17 (2014) 476-481

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Korea Medical Devices Industry Association

Evidence Requirements

Table 2 – Evidence requirements by HIRA for medical device reimbursement applications, decision appeals, and revaluation.

Application category		Evidentiary requirement
Reimbursement application	New application	Copy of MFDS approval letter
		Details of product price calculation included in the reimbursement application
		Evidence supporting cost-effectiveness
		Documents detailing foreign and domestic utilization of the device
		Details of device composition and componentry
		Supporting reports from the literature
		Other supporting documents
	Decision appeal	Documents detailing the grounds for appeal
		Details of the appeal
		Details of the calculation of the reimbursement price being appealed
		Other supporting documents
Revaluation	Common appraisal	MFDS approval letter
		Evidence supporting cost-effectiveness, including comparative information
		Details of device composition and componentry; product manual
		Product sample
		Import price/manufacturing cost, domestic and foreign market prices
	Value appraisal*	Evidence for clinical efficacy and effectiveness, including patient benefits
		Economic evidence including cost-effectiveness analysis
		Documents supporting R&D costs
		Documents supporting technology creativity and product uniqueness
		Foreign government/institution-issued official regulatory documentation
		Other supportive information

HIRA, Health Insurance Review and Assessment Services; MFDS, Ministry of Food and Drug Safety.
* The additional documents required if a premium reimbursement price is sought.

Lee SS, Salole E. Value in Health 17 (2014) 476-481

Revised Value Appraisal System (VAS)

- Application of Multi-Criteria Decision Analysis (MCDA)

Table 1. Two value appraisal tracks differentiated by evidence requirements[20]

Track	Appraisal category	Evidence requirement for appraisal	Maximum premium rate (%)
1	Clinical usefulness (A) Cost effectiveness (C) Technology innovation (D)	Clinical study literature or clinical study report submitted for MFDS approval	100
2	Clinical usefulness (B) Cost effectiveness (C) Technology innovation (D)	Technical File and others submitted for MFDS approval	50

MFDS: Ministry of Food and Drug Safety

Lee SS, Choi HS, Strachan L. Appraising the Value of Medical Device Innovation in South Korea: Multi-Criteria Decision Analysis Application for Reimbursement Coverage Decision-Making. J Health Tech Assess 2015;3(2):90-98

Revised Value Appraisal System (VAS) *cont'd*

Table 2. Revamped Value Appraisal Standard:[20] evaluation criteria by appraisal category

Appraisal category	Factors	Weight	Score
Clinical usefulness (A)			
A1. Therapeutic effects improvement	• Impacts on disease progress, symptom and efficacy, etc. - clinical outcomes such as symptom relief, life extension, recovery, etc. compared with similar products	7	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐
A2. Adverse effect improvement	• Level of adverse effect reduction - short- and/or long-term safety and significant adverse effects compared with similar products - hazard reduction to human - prevention of infection risk to patient and healthcare professional	6	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐
A3. Patient quality of life improvement	• Improvement of patient quality of life - patient's ease of use and independence - patient pain or discomfort - patient satisfaction (minimization of invasiveness and negative impacts on social life)	6	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐

Lee SS, Choi HS, Strachan L. J Health Tech Assess 2015;3(2):90-98

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Revised Value Appraisal System (VAS) *cont'd*

Clinical usefulness (B)			
B1. Functional improvement	• Improvement of product functional aspects	5	0 ☐
	- functional improvement, e.g., fixation strength		1 ☐
	- material improvement (absorbability, biocompatibility, etc.)		2 ☐
			3 ☐
			4 ☐
B2. Procedural easiness	• Improvement of operator's convenience	4	0 ☐
	- procedural success rate enhancement with procedural easiness		1 ☐
	and accuracy		2 ☐
	- procedure time reduction		3 ☐
	- anesthetic time and radiation exposure time reduction		4 ☐
	- invasiveness reduction		
	- technological standardization (minimization of impact from		
	operator's technical skill)		

Lee SS, Choi HS, Strachan L. J Health Tech Assess 2015;3(2):90-98

Revised Value Appraisal System (VAS) *cont'd*

Cost effectiveness (C)	• Cost effectiveness over similar products	3	0 ☐
	- reduction of repetitive procedure with increased product longevity (i.e., implant durability and battery longevity enhancement)		1 ☐
	- cost saving with change in replacement cycle and number of usage		2 ☐
	- cost saving of alternative medical devices or drugs consumption		3 ☐
	- cost saving of hospitalization and treatment period		4 ☐
	- cost saving of procedural time and human resource inputs (physician, nurse, etc.)		
	- cost saving of post-treatment items (diagnostic and testing) frequency or unit cost and rehabilitation		
Technology innovation (D)	• Accreditation or award on technology innovation	3	0 ☐
	- national official accreditation about healthcare technology R&D (new excellent technology, etc.)		1 ☐
	- relevant award record		2 ☐
	- described in textbook and clinical guideline		3 ☐
	- value recognition record for reimbursement coverage decision in foreign countries		4 ☐

R&D: research and development

Lee SS, Choi HS, Strachan L. J Health Tech Assess 2015;3(2):90-98

KMDIA 사단법인 한국의료기기산업협회 Korea Medical Devices Industry Association

Revised Value Appraisal System (VAS) *cont'd*

Table 3. Revamped Value Appraisal Standard:[20] application of appraisal result

Scoring system of premium reimbursement pricing for value appraised new devices			
Value appraisal for Track 1 (appraisal category: A, C, and D)		Value appraisal for Track 2 (appraisal category: B, C, and D)	
Total score	Premium rate (%)	Total score	Premium rate (%)
≥20–<30	10	≥20–<30	10
≥30–<40	20	≥30–<40	20
≥40–<50	30	≥40–<50	30
≥50–<60	40	≥50–<60	40
≥60–<70	50	60	50
≥70–<80	60		
≥80–<90	70		
≥90–<95	80		
≥95–<100	90		
100	100		

Premium rate is calculated by multiplying weight and score in each category and summate total scores (∑weight×score). Additional 5% premium can be added to the calculated premium if clinical evidences generated from the research-oriented hospitals or clinical research centers which are designated by MoHW are submitted to the reimbursement application. MoHW: Ministry of Health and Welfare

Lee SS, Choi HS, Strachan L. J Health Tech Assess 2015;3(2):90-98

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Revised Value Appraisal System (VAS) *cont'd*

Table 4. Hierarchy of clinical literature[25)]

Category	Clinical literature
1	Systematic review based on randomized controlled trial (systematic review, meta-analysis)
2	Randomized controlled trial Systematic review based on category 3 literature
3	Quasi-randomized controlled trial, quasi-RCT Cohort study Case control Study Observational, analytic study
4	Cross sectional study Case series, case report Before/after study Non-analytic study
Others	Not applicable

RCT: Randomized Controlled Trial

Lee SS, Choi HS, Strachan L. J Health Tech Assess 2015;3(2):90-98

Revised Value Appraisal System (VAS) *cont'd*

Table 5. Cochrane collaboration's tool for assessing risk of bias (adapted from Higgins et al.)[26]

Source of bias	Judgment (risk of bias)	Risk of bias	Decision base (directly cited from publication)
Random sequence generation	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence	☐ Low ☐ High ☐ Unclear	
Allocation concealment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment	☐ Low ☐ High ☐ Unclear	
Blinding of participants and personnel	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study	☐ Low ☐ High ☐ Unclear	
Blinding of outcome assessment	Detection bias due to knowledge of the allocated interventions by outcome assessment	☐ Low ☐ High ☐ Unclear	
Incomplete outcome data	Attrition bias due to amount, nature, or handling of incomplete outcome data	☐ Low ☐ High ☐ Unclear	
Selective reporting	Reporting bias due to selective outcome reporting	☐ Low ☐ High ☐ Unclear	
Anything else, ideally pre-specified	Bias due to problems not covered elsewhere	☐ Low ☐ High ☐ Unclear	

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Revised Value Appraisal System (VAS) *cont'd*

Table 6. Risk of Bias for Nonrandomised Studies (RoBANS)[27]

Domain	Details	Risk of bias	Decision base (directly cited from publication)
Comparability of control group	Selection bias caused by the inadequate selection of control group	☐ Low ☐ High ☐ Unclear	
Selection of participants	Selection bias caused by the inadequate selection of participants	☐ Low ☐ High ☐ Unclear	
Confounding variables	Selection bias caused by the inadequate confirmation and consideration of confounding variable	☐ Low ☐ High ☐ Unclear	
Measurement of exposure	Performance bias caused by the inadequate measurement of exposure	☐ Low ☐ High ☐ Unclear	
Blinding of personnel for outcome assessments	Detection bias caused by the inadequate blinding of the personnel for outcome assessments	☐ Low ☐ High ☐ Unclear	
Outcome assessment	Detection bias caused by the inadequate methods for outcome assessment	☐ Low ☐ High ☐ Unclear	
Incomplete outcome data	Attrition bias caused by the inadequate handling of incomplete outcome data	☐ Low ☐ High ☐ Unclear	
Selective outcome reporting	Reporting bias caused by the selective reporting of outcomes	☐ Low ☐ High ☐ Unclear	

Lee SS, Choi HS, Strachan L. J Health Tech Assess 2015;3(2):90-98

Publication about Korea pricing rules

VALUE IN HEALTH 17 (2014) 476–481

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journal homepage: www.elsevier.com/locate/jval

Medical Device Reimbursement Coverage and Pricing Rules in Korea: Current Practice and Issues with Access to Innovation

Sang-Soo Lee, MBA[1,*], *Eugene Salole, MPH, PhD*[2]

[1]*Medtronic Korea Co. Ltd., Seoul, South Korea;* [2]*Value-Based Access Pty Ltd., Sydney, Australia*

ABSTRACT

The development of health funding policy in
country's rapid economic development, v
National Health Insurance (NHI) system in pla

JoHTA

Review Article

J Health Tech Assess 2015;3(2):90-98 ISSN 2288-5811

Appraising the Value of Medical Device Innovation in South Korea: Multi-Criteria Decision Analysis Application for Reimbursement Coverage Decision-Making

Sang-Soo Lee[1], Hyunsook Choi[1], and Liesl Strachan[2]

[1]Medtronic Korea Ltd., Seoul, Korea

[2]Medtronic PLC, Sydney, Australia

New Health Technology Assessment program

- New Health Technology Assessment(nHTA) program was introduced in 2007
- It is limited to new medical technology requiring new procedural technique and indications
- It blocks patient access if fails to pass
- Systematic Review method is applied
- Economic evaluation is not required
- It is **quite different from** HTA programs in other countries
  - HTA is not simple “yes/no” decision method

New Health Technology Assessment program *cont'd*

Health technology assessment (HTA) according to Banta is defined as a multidisciplinary activity that systematically examines technical performance, safety, clinical efficacy and effectiveness, cost, cost–effectiveness, organizational impact, social consequences, as well as legal and ethical aspects of the application of a health technology. The term derives from the political and social debates about environmental and social consequences of technologies in the 1960s and 1970s. Health technologies according to the former U.S. Office of Technology Assessment "are the drugs, devices, procedures, and the organizational support systems within which health care is delivered". Given this broad context, HTA is not defined by a set of methods, but by its intention. The goal of HTA is to provide input to decision-making in policy and practice and to ensure value for money.

systematic methods for observational studies. It should be recognized that HTA can inform and advise but not replace choices, decisions and actions made by politicians, professionals, payers and users. There is a need to distinguish between maximum possible effect of technology (efficacy) from actual provider performance (effectiveness).

Institutionalisation of Health Technology Assessment. WHO Regional Office for Europe; 2001. http://www.euro.who.int/__data/assets/pdf_file/0016/120247/E72364.pdf

ご清聴ありがとうございました

Thank You for Your Attention

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KMDIA 사단법인 한국의료기기산업협회
Korea Medical Devices Industry Association

1st Japan-Korea Joint Symposium on Medical Products

Activity of Compliance Business Ethics Committeiee of JFMDA

June 23, 2016

Shinichirou Nakashima
Chairman of CBEC

医機連 日本医療機器産業連合会 JFMDA The Japan Federation of Medical Devices Associations

The Japan Federation of Medical Devices Associations （URL：http://www.jfmda.gr.jp/）

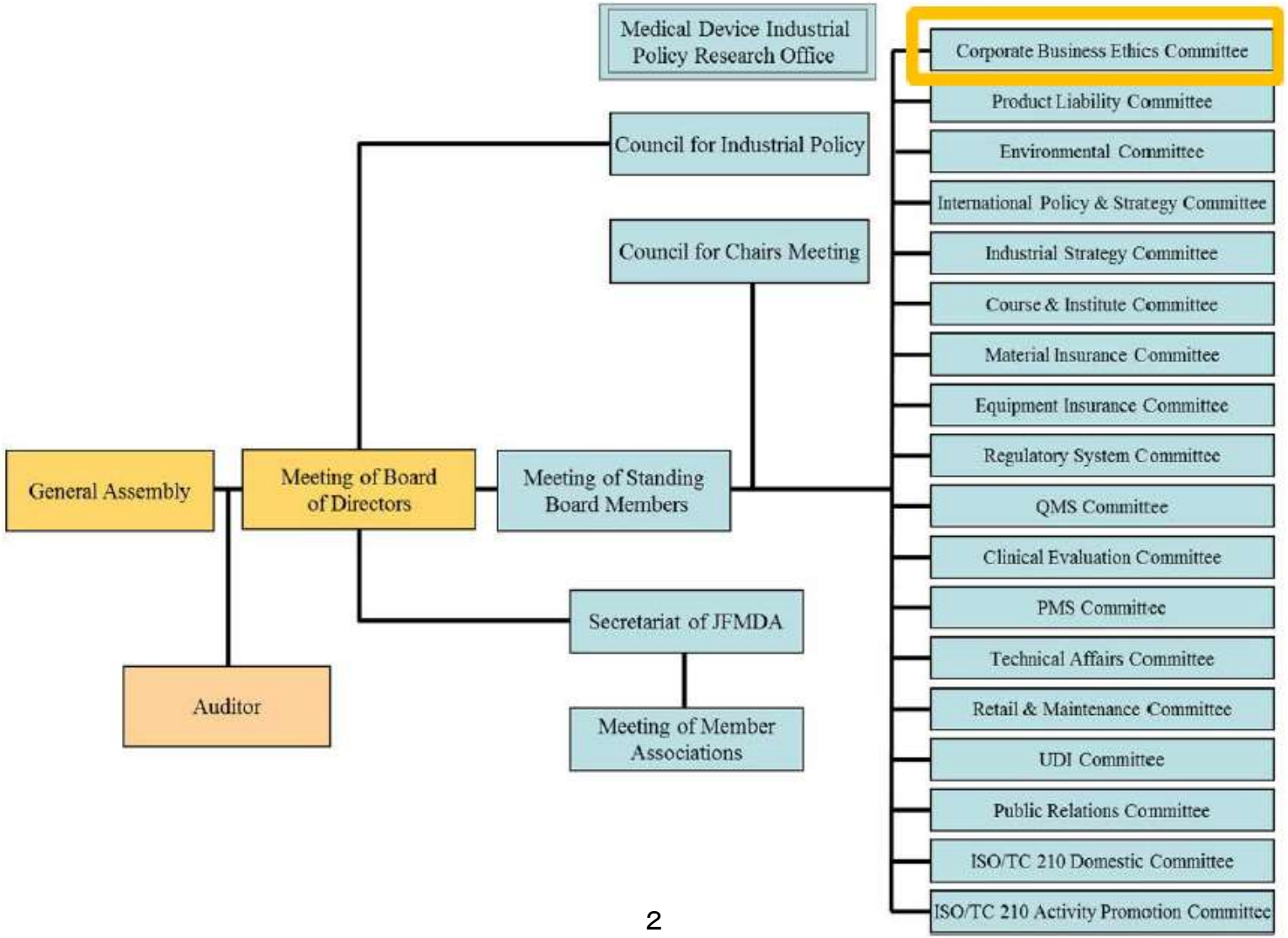
Consists of 21 associations (representing about 4,300 companies (as of April, 2016))

Activities

- Committees : Investigation and study of common issues, Proposal to the government
- Globalization: Harmonization and communication with oversea organizations
- Information: Collecting and delivering information, holding seminar s
- Cooperation with the government: Communication and coordination with related ministries such as MHLW, METI

HAPI	The Japan Home-health Apparatus Industrial Association
JACRI	Japan Association of Clinical Reagents Industries
JAHID	Japan Association of Health Industry Distributors
JAIMA	Japan Analytical Instruments Manufacturers' Association
JAMDI	Japan Association of Medical Devices Industries
JASS	Japanese Association of Surgical Sutures
JCI	Japan Condoms Industrial Association
JCLA	Japan Contact Lens Association
JDTA	Japan Dental Trade Association
JEITA	Japan Electronics and Information Technology Industries Association
JHHC	Japan Home Health Care Association
JHIDA	Japan Hearing Instruments Dispensers Association
JHIMA	Japan Hearing Instruments Manufacturers Association
JHPIA	Japan Hygiene Products Industry Association
JIPT	Japan Industries Association of Physical Therapy Devices
JIRA	Japan Medical Imaging and Radiological Systems Industries Association
JMIA	Japan Medical Industry Association
JMOIA	Japan Medical-Optical Equipment Industrial Association
JOIA	Japan Ophthalmic Instruments Association
@MD-Net	Association of Japan Medical Devices Network
MTJAPAN	Medical Technology Association of Japan

Organization of JFMDA



Constitution and Purpose of CEBC

1. Composed by elected the members from 21 of the member Organizations
2. As a rule, CBEC has been held every month.
3. Mission

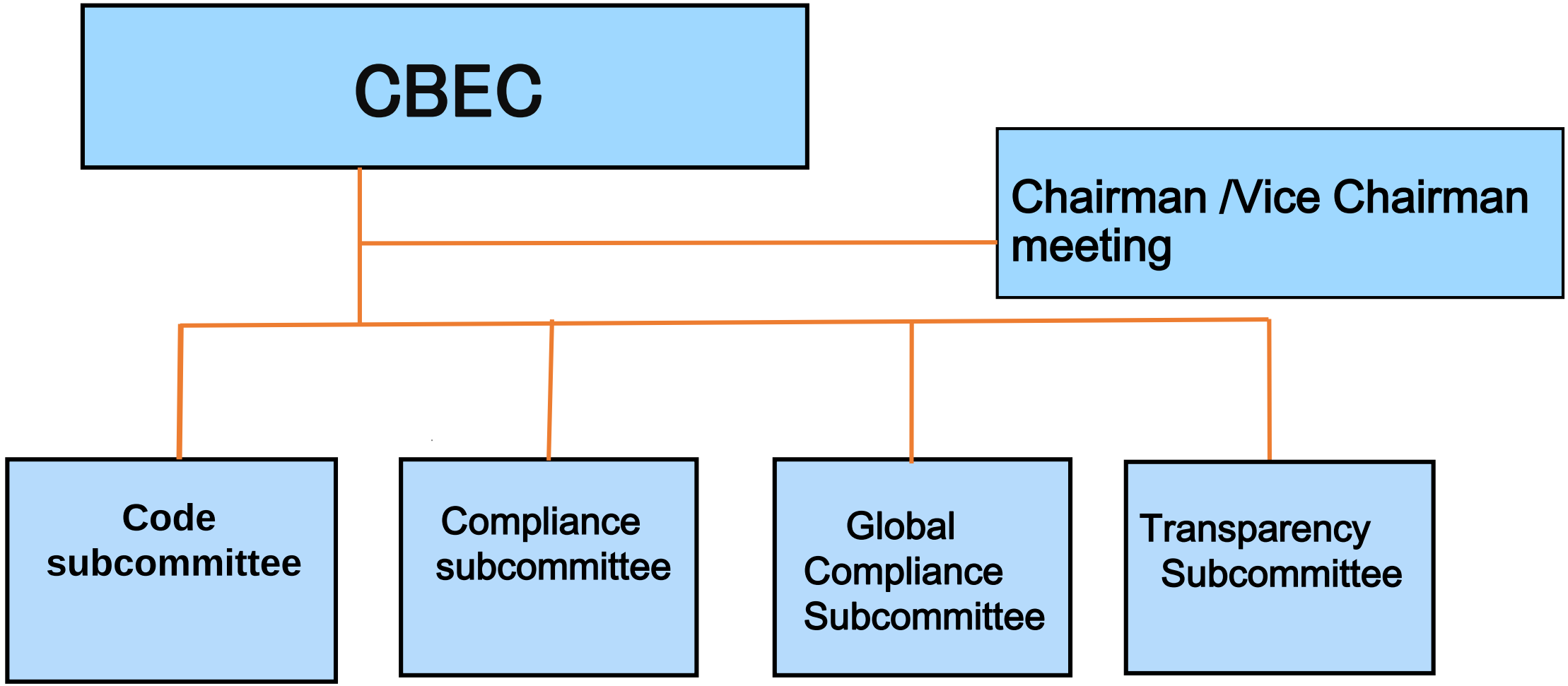
   Enlightement activities for the observance of

   -4 Ethics rules and related guidelines

   -the global laws, regulations and related industry rules.
4. Corresponding at the time of law violation by members companies and the development of measures to relaps prevention.

Organization Chart of CBEC

Aplil 1,2016



Ethics Rules & Guidelines of JFMDA/JFTC

4 Ethics Rules
(JFMDA/JFTC)

1. The Code of Ethics (JFMDA)
2. The Charter of Business Behavior (JFMDA)
3. The Promotion Code of the Medical Devices Industry in Japan (JFMDA)
4. The Fair Competition Code of the Medical Devices Industry in Japan(JFTC).

5 Guidelines
(JFMDA)

1. **Transparency Guidelines**
2. **Guideline for Medical Devices' Advertisement**
3. **Guideline for Medical Devices Exhibition Under Application for Approval**
4. **Guideline for Personal Information Management**
5. **Guideline for Donation to Medical Society**

The Promotion Code of the Medical Devices Industry in Japan（Table of Contents）

I. The Promotion Code of the Medical Devices Industry

6. Advertising/Promotion

- Compliane with Relevant Laws and Regulations -

➢ Pharmaceutical and Medical Device Act

Chapter10　Advertisement of Pharmaceutical and Medical Device

Article 66 : Extravagant advertisement (prohibition on false or exaggerated ad.)

Article 67 : Restriction on advertisement of specified pharmaceutical products

Article 68 : Prohibition on advertising unapproved pharmaceutical products

➢ Standard for Adequate Advertisement of Pharmaceutical Products

6. Advertising/Promotion

- Compliance requirement of Advertising and Promotion

（1）Intended Use and Efficacy of Products

（2）Safety and Effectiveness of Products.

（3）Information not only on Effectiveness but also on Safety,

（4）Comparing Products with Other Companies’ Products.

（5）Defamation or Slander Other Companies or Their Products.

（6）Picking Up Only Exceptional Data

（7）Misleading Expressions, Degrading Photos or Illustrations

（8）Specification of Information such as Brand Name, Regulatory Category, Generic Name, and Reimbursement Coverage in the Medical Insurance

（9）Organization an In-house Review and Control Committee for Printed Materials and Advertisements.

Complaint Review System of The Promotion Code

Ⅰ. Background

Increase in complaints from other member companies that were damaged by The Promotion Code violation of the member companies

Ⅱ. Purpose

Support of rapid and accurate resolution of the dispute between the member companies by objective investigation and judgment of The Promotion Code violation fact

Ⅲ. System Summary

(1) In principle the resolution between the parties
(2) In the case can not be resolved between the parties, complaints to the associations secretariat
(3) Examination in The Review Conference to be installed in CBEC
(4) External Lawyer participated in the Conference
(5) Corrective measures are imposed in violation company

Main Activities of 2015, 2016

1. Compliance Awareness month and Compliance Seminar

2. Revision of Promotion Code（in relation to the revision of the Pharmaceutical affairs Law）

3. Promotion of the information disclosure based on the Transparency Guideline

4. Enactment of “ Regulation for Compliance with Competition Laws”

5. Enactment of “Practical Policy on Clinical Study of Medical devices that have already been approved”

6. Awareness and Support of Anti- Bribery

7. Attendance of APEC Business Ethics forum for SMEs

8. Strengthening of Cooperation with AdvaMed

9. Construction of the Complaint Review System of Promotion Code

10. Restructuring of CEBC organization（Change to the corresponding possible organization for a wide range of compliance theme)

11. Correspondence with the Ministry of Health, Labor and Welfare on the Bill of Clinical Study Law（ongoing）

Compliance awareness Month and Compliance Seminar

Publication

Promotion of the Information disclosure based on the Transparency Guideline

Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations

The objective of these guidelines is to gain a wider understanding that by ensuring transparency and credibility in the business activities of member companies with medical institutions and other organizations, the medical device industry can contribute to the development of medicine, medical technology and all life sciences as well as guarantee a high level of ethics in business activities.

1. **The member companies shall use these guidelines to establish their own transparency guidelines as standards for behavior. The companies will implement the following procedures as preparation.**

（1） Draw up procedures to obtain approval for information disclosure from the medical institutions and other organizations (procedures for trust agreement as prerequisite for information disclosure, etc.)

（2） Establish a system for the early compilation and release of payment information

2. **It is desirable that the company include the following items in its transparency guidelines.**

（1） Basic policies as a member company

Member companies in all their activities shall follow in both word and spirit the "Code of Ethics," the "Charter of Business Behavior" and the 'Promotion Code of the Medical Device Industry" which were established by the JFMDA as well as the "Fair Competition Code of the Medical Device Industry" which was established by the Japan Fair Trade Council of the Medical Device Industry. Member companies shall also set forth their corporate policies for transparency in their dealings with medical institutions and other organizations.

（2） Disclosure methods

Member companies shall disclose compensation provided during the previous fiscal year through their websites or other method after the settlement of accounts.

（3） Timing of disclosure

Payments made during fiscal year 2013 shall be disclosed in fiscal year 2014.

（4） Scope of disclosure

A. Research and development expenses

This includes expenses for trials, reports, and surveillance studies conducted under public regulations (clinical trials for new devices, post-marketing clinical studies, nonconformity and infection case reports, post-marketing surveillance studies, etc.) in addition to those for independent investigations.

- Joint research expenses
  Total annual amount
- Contract research expenses
  Total annual amount
- Clinical trial expenses
  Total annual amount
- Post-marketing clinical study expenses
  Total annual amount
- nonconformity and infection case reporting expenses
  Total annual amount
- Post-marketing surveillance expenses
  Total annual amount

B. Academic research support expenses

This includes expenses for scholarships, general and academic conference donations, as well as academic conference co-sponsoring expenses.

- Scholarship donations
  Department, university, number of cases, amount
- General donations
  University/foundation, number of cases, amount
- Academic conference donations
  Conference number, amount
- Academic co-sponsoring expenses
  Conference number, seminar, amount

C. Manuscript writing fees, etc.

This includes expenses for lectures, manuscript writing, and the consignment of services, including consulting, to provide information regarding the appropriate use of medical devices.

- Lecturers fees
  Professor/director, department, university/hospital, number of cases, amount
- Manuscript writing/supervising fees
  Professor/director, department, university/hospital, number of cases, amount
- Expenses for the consignment of services, including consulting
  Professor/director, department, university/hospital, number of cases, amount

D. Expenses related to information provision

This includes expenses for lectures, workshops, and seminars to provide healthcare professionals with information regarding appropriate and safe use of medical devices.

- Lecture expenses
  Total annual number of cases and amount
- Seminar expenses
  Total annual number of cases and amount
- Expenses for the provision of medical/medical engineering-related literature, etc.
  Total annual amount

E. Other expenses

Expenses for receptions and social courtesy

- Reception expenses
  Total annual amount

Regulation for Compliance with Competition laws

[Compliance Requirements]

"Participants of this assembly are not allowed to talk about the following items during this assembly, as well as before and after this assembly, except when such item is already made public.

- Matters related to prices or volume of products/service;
- Matters related to biddings;
- Matters related to capabilities, plans or policies concerning development, production and sales; and
- Other items specifically related to important measures for competition.

If you are not sure whether an item falls under any of the above, you should refrain from talking about the item."

Awareness and Support of Anti-corruption

1. Notification from Chairman of JFMDA

"For thorough compliance towards the Anti-corruption" July 2, 2015

2. Support tools for member company

1）Template of Top message towards Anti-corruption

2）Standard inner rule of conducting Public officials

3）Template of Pledge on compliance by all employees

Attendance of APEC Business Ethics Forum for SMEs

APEC Business Ethics Forum for SMEs
Medical Device Sector Workshop

Potential conflicts of interest between healthcare companies and physicians are a particular concern.

⇩

To establish Code of Ethics

2014 1st Forum, Nanjing

2015 2nd Forum, Manila

Thank you for your attention.

JFMDA
The Japan Federation of
Medical Devices Associations

KMDIA

Korea Medical Devices Industry Association

Promotion code of KMDIA & Anti-corruption law

Kyeong-Yun BAEK/ KMDIA

Jun. 23, 2016

Promotion Code of KMDIA

*KMDIA (Korea Medical Devices Industry Association)

*制定: 2011年 1月 12日

*公正取引委員会承認: 2011年10月 28日

Promotion Code of KMDIA

※Background：医療法、薬事法、医療機器法の改定(2010.5.27) ⇒ リベート双罰制

医者、薬剤師などは製薬メーカなどから**販売促進の目的にて不当な経済的利益 を受けることが出来ない。**(但し、保健福祉部令にて決める事項は例外として認められる)⇒**原則的禁止、例外的認定**

対　象	医者、薬剤師など （薬剤師、漢方薬剤師、医療人、医療機関開設者、従事者(法人代表者及び従事者を含む)
経済的利益	**金銭、物品、便益、労務、饗応、その外の経済的利益**

Promotion Code of KMDIA

※ リベート双罰制での例外的な許容範囲（7つ項目）

1.見本提供

2.学術大会支援

3.臨床試験支援

4.製品説明会

5.代金決済条件による費用割引

6.市販後調査

7.その他

※ 違反時の制裁

- 刑事的制裁 : 2年以下の懲役又3千万W以下の罰金/ 経済的利益は没収・追徴
- 行政的制裁 : 提供者は業務停止より許可取消し・営業所閉鎖、収受者は12ヶ月内の免許資格停止

Promotion Code of KMDIA

※KMDIA Promotion Codeで
許容される経済的な利益などの範囲（12項目に細分化）

- 6条.見本の提供
- 7条.寄付行為
- 8条.学術大会開催・運営支援
- 9条.学術大会への参加支援
- 10条.自社製品説明会
- 11条.教育・訓練
- 12条.講演・諮問
- 13条.臨床試験用の医療機器の提供及び貸し出し
- 14条.市場調査
- 15条.市販後調査（PMS）
- 16条.市販後調査外の臨床活動
- 17条.展示・広告

Promotion Code of KMDIA

※KMDIA Promotion Codeの運用（12項目）

条項	運用と許容範囲（製造業者、輸入業者のみ）
見本の提供	•1-2個、患者請求できない、設備は1カ月まで •販売業者も提供可能
寄付行為	•KMDIAに寄託　or •KMDIAで公知/申請/審議/報告
学術大会開催・運営支援	•国内学会：学会申請/審査/KMDIA公知/事業者申請/報告 •国内開催国際学会：学会申請/KMDIA公知/事業者申請/報告
学術大会への参加支援	•KMDIAで公知、対象はFacultyのみ、Faculty指名は不可 •使用経費は学会が精算後KMDIAに申請（実費交通費、登録費、食費、宿泊費）、KMDIAは確認後のメーカーに通知 •メーカはKMDIAに支払

Promotion Code of KMDIA

※KMDIA Promotion Codeの運用（12項目）

条項	運用と許容範囲（製造業者、輸入業者のみ）
自社製品説明会	•宿泊を伴う場合は40日前事前申請/審議/報告 •食事費1食10万W/人以下、1日15万W/人以下 •宿泊費20万W以下、記念品5万W以下、交通費
教育・訓練	•宿泊を伴う場合と海外での研修は40日前事前申請/審議/報告 •海外での研修は韓国で登録され未輸入品のみ •支援費用範囲；自社製品説明会と同一
講演・諮問	•講演；10人以上、40分以上、50万W/H、100万W/日、200万W/月 •諮問；50万W/回、300万W/年 •KMDIA報告
臨床試験用の医療機器の提供及び貸し出し	•MFDSで承認、IRBで承認受けた臨床試験用のみ

Promotion Code of KMDIA

※KMDIA Promotion Codeの運用（12項目）

条項	運用と許容範囲（製造業者、輸入業者のみ）
市場調査	•市場調査機関依頼のみ10万W以下飲食料orお礼品、お礼金 •KMDIA報告
市販後調査 （PMS）	•MFDSの指示によるもの
販後調査外の 臨床活動	•MFDSで承認、IRBで承認受けた臨床 •費用の会計処理時に研究結果報告書添付
展示・広告	•Web広告；1000万W/年 •Booth : 50万W ~ 300万W/Booth (Max. 2booth) •学会誌への広告: 60万W~150万W/Page •KMDIA報告

Anti-Corruption Law in Korea

Anti-Corruption Law in Korea

法令名	内容/特徴
刑法	**賄賂罪**及び背任収.贈財罪
特定犯罪加重処罰等 に関する法律	**賄賂罪加重処罰**、 政府管理企業役員、職員含む
腐敗防止及び国民権益委員会の設置と運営に関する法律（腐敗防止法）	内部告発者保護及び褒賞
公務員行動綱領	**公務員の行動基準提示**
国際商取引での外国公務員に対する賄賂防止法	外国公務員賄賂防止法、 アメリカのFCPAと類似
国を当事者とする契約に関す法律 (国家契約法)	2年まで国家入札参加禁止

Anti-Corruption Law in Korea

※公務員に対する賄賂罪(現)

区分	内容
処罰	供与者 : 5年以下の懲役又は2千万W以下の罰金
	取得者: 賄賂額により最大無期懲役
構成要件	公務員: 政府公務員、準政府公務員、準公務員含む
	賄賂: 一体の有/無形の利益
	“職務関連性”と “対価性” が立証されること

不正請託及び金品等授受禁止法」
(不正請託禁止法/金英蘭(キム・ヨンラン)法

*制定: 2015年 3月 27日

*施行令立法予告: 2016年 5月 13日

*施行: 2016年 9月 28日 (予定)

不正請託禁止法の構成

第1章 総則

第2章 不正請託禁止

第3章 金品等の授受禁止

第4章 不正請託等の防止に関する業務の総括

第5章 懲戒及び罰則

付則

不正請託禁止法の構成

第1章 総則

- 第2条(定義) : **公職者などの定義**

ア. 国家公務員法又は地方公務員法による公務員とその他公務員として認定された者

イ.公職有閑団体及び機関の長と役員・職員

ウ.各級学校の長と教職員及び学校法人の役員・職員

エ.言論社の代表者と役員・職員

不正請託禁止法の構成

第2章 不正請託禁止

- 第5条(不正請託禁止) : だれでも直接又は第3者を通じて職務を行う公職者などに不正請託をすることを禁止する。**(Point : 金品授受可否に関係ない)**

※不正請託とは?

- 法令を違反して処理するか影響を及ぼすようにする行為

不正請託禁止法の構成

第3章 金品等の授受禁止

- 第8条(金品等の授受禁止)

① 職務に関係なく、同一人から1回に100万W又は毎会計年度に300万Wを超過する金品等禁止

② 職務に関連して、100万W以下金品などの授受禁止

※職務関連性があれば対価性可否と金品などの規模を問わずに処罰

不正請託禁止法の構成

第3章 金品等の授受禁止

- 第8条(金品等の授受禁止)

③ 例外条項 (第8条 第3項)

1.公共機関が所属公職者などや派遣公務員などに支給したり、上級公職者などが上及び激励及び賞などの目的のために下級公職者などに提供する金品等

2.円滑な職務遂行または社交及び儀式や扶助の目的にて提供される食物、慶弔費及びギフトなどとして、大統領令で定める価額の範囲内の金品等　（施行令（案）：食物3万W、ギフト5万W、慶弔費10万W）

不正請託禁止法の構成

第3章 金品等の授受禁止

- 第8条(金品等の授受禁止)

③ 例外条項 (第8条 第3項)

3.私的取引(贈与は除く)による債務の履行など正当な権原によって提供される金品など

4.公職者等の親族(「民法」第777条の規定による親族をいう。)が提供する金品等

不正請託禁止法の構成

第3章 金品等の授受禁止

- 第8条(金品等の授受禁止)

③ 例外条項 (第8条 第3項)

5.公職者などと公職者などに関連する従業員互助会、同好会、同窓会、郷友会、懇親会、宗教団体、社会団体などが定める基準に基づいてメンバーに提供する金品等とその所属メンバーなど公職者などと特別に長期的及び継続的な親交関係を結んでいる者が病気及び災害などで困難な境遇にある公職者等に提供する金品等

不正請託禁止法の構成

第3章 金品等の授受禁止

- 第8条(金品等の授受禁止)

③ 例外条項 (第8条 第3項)

6.公職者などの職務に関連する公式イベントで、主催者が参加者に通常の範囲内で一律に提供する交通、宿泊、飲食物などの金品など

7.不特定多数の者に配布するためのお土産や広報用品などやコンテスト及び抽選で受ける報酬や商品など

8.その他他の法令及び基準又は社会常規に基づいて許可されている金品など

不正請託禁止法の構成

第3章 金品等の授受禁止

- 第10条（外部講義などの報酬授受制限）

＜外部講演礼金の上限額基準/単位:KRW＞

公務員行動綱領（現行）	不正請託禁止法施行令（案）
40万（長官級）	50万W（長官級）
30万（次官級）	40万（次官級・公職関連団体の機関長）
23万（4級以上）	30万（4級以上・公職関連団体の役員）
12万（5級以下）	20万（5級以下・公職関連団体の職員）
-	100万（言論人・私立学校の教職員）

不正請託禁止法の構成

第4章 不正請託等の防止に関する業務の総括

- 業務の館長:国民権益委員会

第5章 懲戒及び罰則

- 第21条(懲戒)
- 第22条(罰則)
- 第23条(過料賦課)
- 第24条(両罰規定)

付則:2016年 9月 28日より施行

THANK YOU

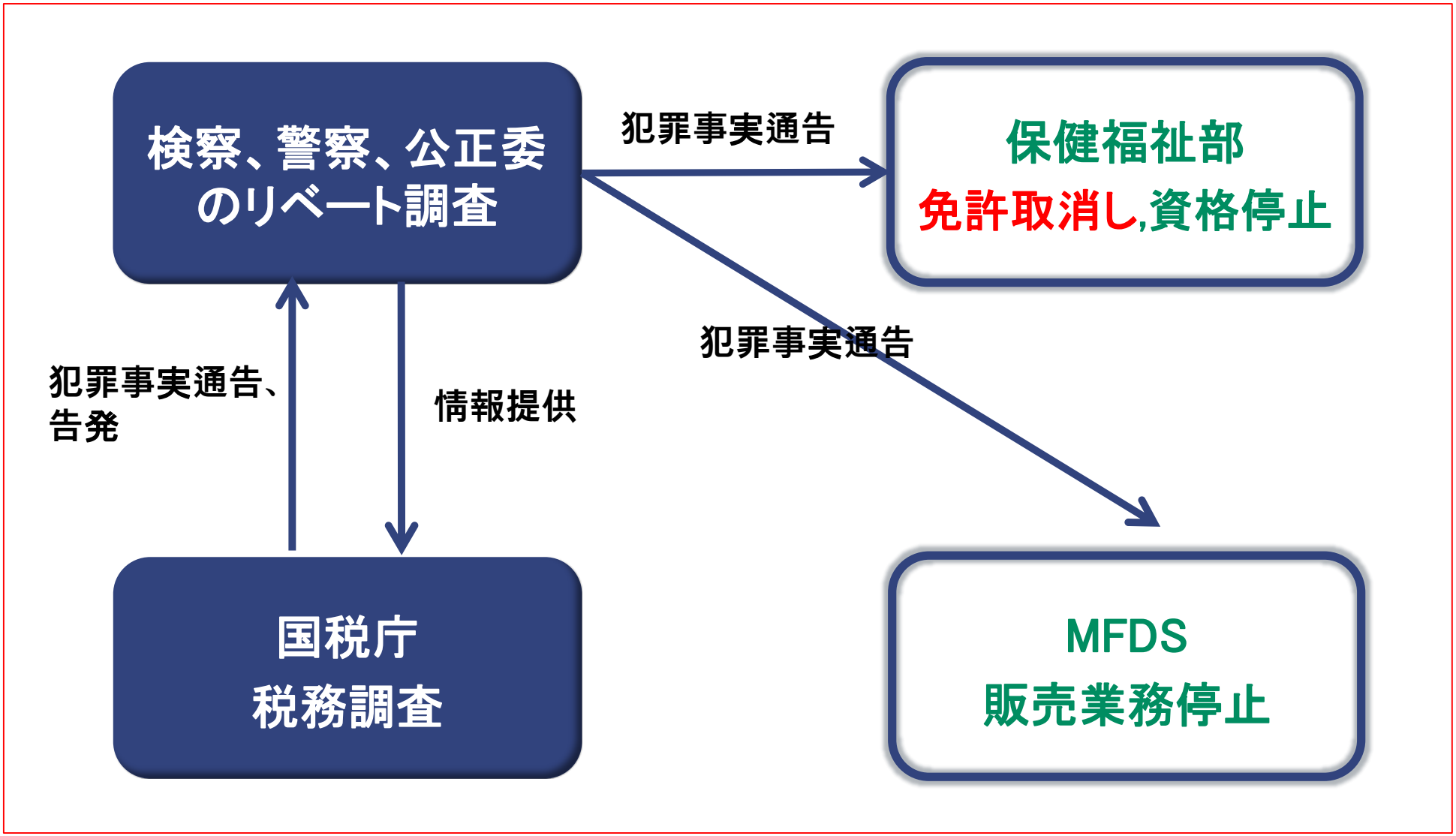
別添

別添1.リベート双罰制での許容範囲

※ 例外的な許容範囲（7つ項目）

許容行為	許容範囲
1. 見本提供	最少包装単位に見本又はsampleの文字を表示して提供。 医療機器の形態などを確認するのに必要な最少数量。 患者さんに販売禁止
2. 学術大会支援	国内外の学術大会へ参加する発表者、座長、討論者が学術大会の主催者より支援して貰う実費の交通費、食費、宿泊費、登録費
3. 臨床試験支援	臨床試験に必要な臨床試験用医療機器及び研究費
4. 製品説明会	*10万ウォン以下の飲食費、5万ウォン以下の記念品、実費の交通費、宿泊 *個別医療機関の訪問の際には1日10万ウォン以下の飲食費（月4回以内及び1万ウォン以下の販促物） *製造業者の海外での製品説明会に講演者として参加する保健医療人支援
5. 代金決済条件による費用割引	決済期間が3ヶ月以内は0.6%以下、2ヶ月以内は1.2%以下、1ヶ月以内は1.8%以下の費用割引
6. 市販後調査	再審査の対象になる医療機器のPMSは件当り5万ウォン以下。追加調査が必要な場合は30万ウォン以下
7. その他	クレジットカードを使う場合は支払い金額の1%以下のポイント

別添2.リベートに関する汎政府空調システム



別添3.機関別処分可能な措置及び根拠法律

政府機関	可能な措置	根拠法律
公正委	課徴金賦課、是正命令、刑事告発	公正取引法
検察/警察	リベート相罰制による刑事処罰	薬事法、医療機器法、医療法
保健福祉部	(1)薬価引下げ (2)医師の資格停止	(1)国民健康保険法 (2)医療法
MFDS(旧KFDA)	当該品目販売業務停止	薬事法、医療機器法
健康保険審査評価院、国民健康保険公団	(1)薬価引下げ (2)詐欺罪刑事告発	(1)国民健康保険法 (2)刑法
関税庁/国税庁	接待費とみて損金否認	法人税法、国税基本法
監査院	是正要求、処分勧告	監査院法