

Meeting of representatives

Secretariat Report

December 08, 2022

EBC Medical Equipment and IVD Committee

15 : 00 - 15 : 15 (15 minutes)

1. Confirmation of meeting completion
2. Appointment of meeting chairman
3. Opening remark - Chairman
 - (R) Summary of Activities in 2022
 - (D) 2023 Activity Policy
4. Report of the Secretariat
 - (D) monthly meeting Schedule
 - (R) Financial Report 2022
 - (D) The 2023 Budget

15 : 15-15 : 30 (15 minutes)

5. Digital Health Task Force
 - 2022 Activity Report
 - 2023 Activity Policy

15 : 30-16 : 10 (40 minutes)

6. MD / Medical Fee Subcommittee
 - 2022 Activity Report
 - 2023 Activity Policy

16:10-16:20

Break

16 : 20-16 : 40 (20 minutes)

7. MD / Pharmaceutical Affairs Subcommittee
 - 2022 Activity Report
 - 2023 Activity Policy

16 : 40-17 : 20 (30 minutes)

8. IVD Subcommittee
 - 2022 Activity Report
 - 2023 Activity Policy

17 : 20-17 : 9. Closing remark _ First Vice Chairman

30 (10 minutes)

Confirmation of meeting completion

As of December 2022, 31 member companies were registered

- Representatives 7 companies
 - Submissions of power attorney 24 companies
 - Chairperson : 17 companies
 - Substitute attendees : 7 companies
 - No response 0 companies
- } 31 companies

Admission

- Corcym Japan Ltd. 2022 Feb.
- ZAP Surgical Japan GK 2022 Nov

Withdrawal

- ◆ Medtronic Japan Co., Ltd. 2022 Jan.

Constitution

**Election of Meeting Chairperson :
Appointed by the Chairperson**

**Teisoku (Article 17) : Attendance of a
majority of members**

**Voting (Article 18) : Majority of
members present**

Chairman's Opening remark

- ◆ Executive Summary of Activities in 2022
 - ◆ Activity Policy for 2023

■ Strengthening policy advocacy activities

- ✓ All completed without delay at the UDI in the final December of the third year of implementation of the Pharmaceutical and Medical Devices Law
- ✓ Expansion of the scope of application for challenge (reevaluation based on the results of use after new listing)
- ✓ Full-scale implementation of MDSAP (Medical Device Single Audit Program) in Japan
- ✓ Clarification of appropriateness and evaluation of programmed medical devices, and reinforcement of review system (PMDA, MHLW consultation desk)
 - Recommendations on cybersecurity and data protection
 - Utilize to the application for RWD and secondary use of medical data including AI
 - Discussion on promotion of MDSRP (Medical Device Single Review Program)
 - Description of the English brand name of the importer in the marketing approval / certificate
 - Measures to Enhance Stable Supply
 - Application of implantable medical device information to medical data
 - Opinions on revision of infectious disease law and infectious disease-related tests
 - Review of the review classification of pathogen gene products (to review them as approval standard products)
 - Revision of the definition of in-vitro diagnostics
 - Revision of qualification requirements for MAH-general of in-vitro diagnostics

■ Deregulation in Japan and Europe

- Mutual acceptance of GCP compliance review results based on multinational clinical trials, etc.
- Webinar on the German Program Medical Device Insurance Scheme DiGA
- Introduction to European Digital Strategy

■ Strengthening relations with related organizations

- Meeting with the new Counselor of the MHLW
- Exchange of opinions with the Pharmaceutical Industry Promotion and Medical Information Planning Division, Health Policy Bureau, MHLW
- Exchange of opinions with the Medical and welfare tool Industry Office, Healthcare Industry Division, Commerce and Service Group, METI
- Cooperation with the Delegation of the European Union to Japan
- Opinion on Stable Supply with AMDD, MTJAPAN
- EBC White Paper

■ Proposal for Medical Fee Revision

- Proposal for an insured provisional approval system for programmed medical devices
- Promotion of preventive medicine - Introduction of low-dose lung cancer computed tomography to Lung Cancer Examination

■ Strengthening policy advocacy activities

Continue :

- Recommendations on cybersecurity and data protection
- Utilize to the application for RWD and secondary use of medical device including AI
- Discussion on promotion of MDSRP (Medical Device Single Review Program)
- Description of the English brand name of the importer in the marketing approval / certificate
- Measures to Enhance Stable Supply
- Application of implantable medical device information to medical data
- Opinions on revision of infectious disease law and infectious disease-related tests
- Review of the review classification of pathogen gene products (to review them as approval standard products)
- Revision of the definition of in-vitro diagnostics
- Revision of qualification requirements for MAH-general of in-vitro diagnostics

■ Deregulation in Japan and Europe

- Mutual acceptance of GCP compliance review results based on multinational clinical trials, etc.
- Opinions on revision of infectious disease law and infectious disease-related tests
- Review of the review classification of pathogen gene products (to review them as approval standard products)
- Revision of the definition of in-vitro diagnostics
- Revision of qualification requirements for production and marketing of in-vitro diagnostics

■ Deregulation in Japan and Europe

- Mutual acceptance of GCP compliance review results based on multinational clinical trials, etc.
- Follow-up on the German Programmed Medical Device Insurance Scheme DiGA
- Study : MDR/IVDR, insurance systems in major European countries, RWD utilization

■ Strengthening relations with related organizations

- Exchange of opinions with the Pharmaceutical Industry Promotion and Medical Information Planning Division, Health Policy Bureau, MHLW, and the Medical Devices Evaluation and Licensing Division, Pharmaceutical and Human Health Bureau
- Exchange of opinions with the Medical and welfare tool Industry Office, Healthcare Industry Division, Commerce and Service Group, METI
- Cooperation with the Delegation of the European Union to Japan

■ Proposal for Medical Fee Revision

- C2 Applicability of New Technology and Predictability of Insurance
- Evaluation Process for Medical Devices Related to Medical Technology Evaluation Proposal
- Proposal for an insured provisional approval system for programmed medical devices
- Innovation Evaluation System for Clinical Testing of In-vitro Diagnostics

Basic Recognition for the Next Revision (146th Social Security Council, Insurance Committee, October 22, 2021)

Key Issues :

◆ Medical Care System for Novel Coronavirus Infections

- Appropriate Role-Sharing in Regional Medicine : Differentiation, Strengthening, and Cooperation
- Evaluation and functional differentiation of Hospital Treatment and outpatient treatment
- High-quality home care

◆ Promotion of work style reform for doctors, etc.

- 2024 Limitation on overtime work for doctors
- Promoting Task Sharing, Task Shifting and Team Medicine
- Securing emergency medical care systems
- Promotion of ICT utilization that contributes to operational efficiency

◆ Other

Online medical care, fertility treatment and high-quality cancer care

Appropriate evaluation of medical technology, etc. based on evidence and relative clinical usefulness

Secretariat Report

Major annual events 2022

January : Practitioners' Meeting (MD/IVD) for Collaborative Planning to Speed Up Medical Device Examination

March : Survey on purchase price and distribution cost

May : **Submission of requirements for stable supply to Minister of MHLW and Minister of METI**

June : Steering Meeting and Prior Meeting for Practitioners' Meeting on Collaborative Planning to Speed Up Medical Device Examination

Revision of the Infectious Diseases Law Industry opinion meeting

Consultations on stable supply : MHLW Economic Affairs Division and METI Medical & Welfare Office

July : Practitioners' Meeting (MD/IVD) for Collaborative Planning to Speed Up Medical Device Examination

Interview with the Director of Medical Device Policy Office, Economic Affairs Division Health Policy Bureau

August : Exchange of opinions of the Pharmaceutical Industry Promotion and Medical Information Planning Division, Health Policy Bureau

Interview with Counselor Health Policy Bureau, MHLW

Medical DX Lecture + Information Exchange Meeting

September : **Periodic Opinion Exchange Meeting** (MHLW / PMDA : Review / Regulatory related)

November : **German DiGA Webinar**

Creation of Innovative Pharmaceuticals, Medical Devices and Regenerative Medicine Products **Public-Private Dialogue**

EBC White Paper

Month 2023,1 : **Regular Meeting** (Medical Fee Related), Practitioners' Meeting (MD/IVD)

Cost-effectiveness
evaluation
System Subcommittee
Activities
Activities of various
committees of the
Federation of Medical and
Monthly meeting

(D) Plan to hold the 2023 monthly meeting and Representatives Meeting

Time : 2 : 30 to 5 : 00 p.m.

Place : Siemens Healthcare, 5th floor conference room / WEB

Dates :

Thursday, January 26

Friday, February 24

Thursday, March 23

Thursday, April 20

Thursday, May 25

Thursday, June 22

Thursday, July 20

August 24th (Thu) + information exchange meeting

Thursday, September 21

Thursday, October 19

Thursday, November 16

December 07 (Thu) Representatives meeting + information exchange meeting

March 2023 forecast

		2022年予算	2022年11月実績	vs. 予算	2023年3月までに発生する予定費用	2023年3月末FC	FC vs. 予算
前年度繰越金	Carry-over from previous year	¥12,353,273				¥12,353,273	
会費	Membership fee	¥5,800,000	¥6,200,000	106.9%	¥0	¥6,200,000	106.9%
情報交換会参加費	Participation fee for information exchange meeting	¥300,000	¥93,000	31.0%	¥120,000	¥213,000	71.0%
その他 (利子等雑収入)	Other (miscellaneous income such as interest)		¥56				#DIV/0!
今年度収入合計	Total revenue for this fiscal year	¥6,100,000	¥6,293,056	103.2%	¥120,000	¥6,413,056	105.1%
収入合計	Total Revenue	¥18,453,273		0.0%		¥18,766,329	101.7%
事務局運営費 (人件費)	Operating expenses (personnel expenses)	¥3,400,000	¥1,518,195	44.7%	¥1,084,425	¥2,602,620	76.5%
代表者会議 + 情報交換会	Representative Meeting + Information Exchange Meeting	¥800,000	¥1,221,000	152.6%	¥390,000	¥1,611,000	201.4%
医機連会費	JFMDA membership	¥600,000	¥600,000	100.0%	¥0	¥600,000	100.0%
調査・翻訳費	Research and translation costs	¥600,000	¥0	0.0%	¥350,000	¥350,000	58.3%
事務局活動費	Secretariat activity expenses	¥80,000	¥43,674	54.6%	¥31,196	¥74,870	93.6%
部会・TF活動費	Expenses for subcommittee and TF activities	¥400,000	¥200,000	50.0%	¥150,000	¥350,000	87.5%
HPメンテナンス費	Hp maintenance cost	¥30,000	¥0	0.0%	¥0	¥0	0.0%
その他 (雑費)	Other (miscellaneous expenses)	¥20,000	¥3,740	18.7%	¥5,000	¥8,740	43.7%
支出合計	Total Expenses	¥5,930,000	¥3,586,609	60.5%	¥2,010,621	¥5,597,230	94.4%
本年度収支決算 (損益分)	Settlement of accounts for this fiscal year (profit and loss)	¥170,000	¥2,706,447			¥815,826	479.9%
本年度繰越金	Current year carry-over)	¥12,523,273				¥13,169,099	105.2%

(D) 2023 Budget (draft)

		2022年予算	2023年3月FC	vs. 予算	2023年予算案	予算 vs. 2023年3月FC	Note
前年度繰越金	Carry-over from previous year	¥12,353,273	¥12,353,273		¥13,169,099		
会費	Membership fee	¥5,800,000	¥6,200,000	106.9%	¥6,200,000	100.0%	
情報交換会参加費	Participation fee for information exchange meeting	¥300,000	¥213,000	71.0%	¥300,000	140.8%	
その他（利子等雑収入）	Other (miscellaneous income such as interest)	¥0	¥0		¥0	#DIV/0!	
今年度収入合計	Total revenue for this fiscal year	¥6,100,000	¥6,413,056	105.1%	¥6,500,000	101.4%	
収入合計	Total Revenue	¥18,453,273	¥18,766,329	101.7%	¥19,669,099	104.8%	
事務局運営費（人件費）	Operating expenses (personnel expenses)	¥3,400,000	¥2,602,620	76.5%	¥3,400,000	130.6%	
代表者会議 + 情報交換会	Representative Meeting + Information Exchange Meeting	¥800,000	¥1,611,000	201.4%	¥1,800,000	111.7%	ヨーロッパ向け情報交換会
医機連会費	JFDA membership	¥600,000	¥600,000	100.0%	¥600,000	100.0%	
調査・翻訳費	Research and translation costs	¥600,000	¥350,000	58.3%	¥600,000	171.4%	
事務局活動費	Secretariat activity expenses	¥80,000	¥74,870	93.6%	¥200,000	267.1%	大使館・商工会議所等
部会・TF活動費	Expenses for subcommittee and TF activities	¥400,000	¥350,000	87.5%	¥3,000,000	857.1%	MDR/IVDR対応、DIGA update
HPメンテ費	HP maintenance cost	¥30,000	¥0	0.0%	¥30,000	#DIV/0!	
その他（雑費）	Other (miscellaneous expenses)	¥20,000	¥8,740	43.7%	¥20,000	228.8%	
支出合計	Total Expenses	¥5,930,000	¥5,597,230	94.4%	¥9,650,000	172.4%	
本年度収支決算（損益分）	Settlement of accounts for this fiscal year (profit and loss)	¥170,000	¥815,826		¥-3,150,000		
本年度繰越金	Current year carry-over)	¥12,523,273	¥13,169,099		¥10,019,099	80.0%	

Thank you for listening.
We look forward to your continued understanding and cooperation in
our activities.

Thank you for your attention
We ask for your continued understanding and cooperation in the
activities of the committee members.