

# **EBC Medical Equipment and Diagnostics Committee**

## **Secretariat Report**

2021.12.09

**欧州ビジネス協会（EBC）医療機器・I V D委員会**

## 15:00 – 15:10 (15 min.)

1. Confirmation of meeting establishment
2. Appointment of chair
3. Greeting from the chairman
  - (R) 2020 activity summary
  - (D) 2021 activity policy
4. Secretariat report
  - (D) Schedule of monthly meeting
  - (R) 2021 accounting report
  - (D) 2022 budget

## 15:15 – 15:20 (5 min.)

5. Mirai project

## 15:20-15:30 (10 min.)

6. Digital health task force

## 15:30 – 16:00 (30 min.)

7. MD/medical fee subcommittee
  - 2021 Activity summary
  - 2022 Activity policy

## 16:00 – 16:20 (20 min.)

8. MD/yakuji subcommittee
  - 2021 activity summary
  - 2022 activity policy

## 16:20 – 16:50 (30 min.)

9. IVD subcommittee
  - 2021 activity summary
  - 2022 activity policy

## 16:50 – 16:55 (5 min.)

10. Closing remarks first vice-chairman

## Number of registered member companies: 30 as of Dec. 2021

- Representative attendance 6
  - Submission of power of attorney 22
- } 28
- Delegation to the chairman : 14
  - Attendance of agent : 8

- Unanswered 2

### Constitution

**Election of chair: Appointed by chairman**

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

**Decision (Article 18): Majority of attending members**

# Greeting from the Chairman

- ◆ 2021 activity summary
- ◆ 2022 activity policy

# (R) 2021 activity summary

## ■ Strengthening of policy advocacy activities

- Request continuous improvement to the Pharmaceuticals and Medical Devices Act (PMD act)
- Actively participate in collaborative plans for medical device regulation and expedited review
- Work on implementation of the revision of the PMD act (governance, UDI, MDSAP, IDATEN, PHOENIX, etc.)

## ■ Deregulation in Japan and Europe

- Promote mutual certification based on European regulatory revisions
- International alignment activities

## ■ Strengthening of relationships with related organizations

- Strengthen relationships with the Ministry of Health, Labor and Welfare, PMDA, Ministry of Economy Trade and Industry, Ministry of Internal Affairs and Communications, etc.

## ■ Activities for the 2022 revision of medical fees

- Create a new medical fee system - Towards 2022
- Develop market for preventive medicine and preemptive medicine

### eHealth

Collab. plans / working-level meetings

**IDATEN + AI, PHOENIX**  
**eIFU, UDI, MDSAP,**  
**MDSRP(GRRP)**

Regular discussion meeting

Dissemination of MDR/IVDR info.  
ISO14971, IEC62366-1

### DiGA Webinar/APAC Medical Policy Bureau

- eHealth data utilization

- Exchange of opinions with the  
Economic Affairs Division

### Pharmaceutical, Living and Hygiene Bureau

- MDR/IVDR study session  
DX – review processes]

### Health data

**AI**

**C2 challenge**

**Telemedicine / robot**

Regular meeting

# (D) 2022年活動指針

## ■ Strengthening of policy advocacy activities

- Request continuous improvement to the Pharmaceuticals and Medical Devices Act (PMD act)
- Actively participate in collaborative plans for medical device regulation and expedited review
- Work on implementation of the revision of the PMD act (bar code display on packing, etc.)

## ■ Deregulation in Japan and Europe

- Promote mutual certification based on European regulatory revisions
- International alignment activities

## ■ Strengthening of relationships with related organizations

- Strengthen relationships with the Ministry of Health, Labor and Welfare, PMDA, Ministry of Economy Trade and Industry, Ministry of Internal Affairs and Communications, etc.

## ■ Activities for the 2023 revision of medical fees

- Create a new medical fee system - Towards 2023
- Develop market for preventive medicine and preemptive medicine

## eHealth

Collab. plans / working-level meetings

**MDSAP follow-up**

**MDSRP(GRRP) trends**

Regular discussion meeting

Dissemination of MDR/IVDR info.

- EU Data Policy

- DiGA follow-up

## Medical Policy Bureau

- **eHealth data utilization**

## Pharmaceutical, Living and Hygiene Bureau

- MDR/IVDR study session

- **DX – review processes]**

## **Special materials:**

Foreign price / functional classification / innovation of diagnostic treatment equipment  
Program medical device + AI  
C2 challenge

Telemedicine / robot

**IVD R6 medical fee revision support**

Regular meeting

# Report from Secretariat

# 2021 activity summary

## Major annual events in 2021

**Feb.** Reiwa 2 regular meeting (medical fees related)

**Mar.** Submission of medical fee revision request

**Apr.** IDATEN, PHOENIX, APAC med study session

**Apr.-Jun.** Discussions with the Data Health Promotion Special Committee (Liberal Democratic Party)

**Jul.** PMDA : Meeting for MDSAP April 2022 full-scale introduction

Reiwa 3 regular meeting (medical fees related)

Established Digital Health Task Force

**Aug.** Regular discussion meeting (related to the PMD act)

Irish Government Commerce Agency Office in Japan

"Information on the Irish Medical Device Industry"

**Sep.** DiGA (German program medical device insurance listing program) webinar held

(Ministry of Health, Labor and Welfare, PMDA, industry)

**Oct.** Exchange of opinions with the Economic Affairs Division (Chief Ando, Chief of Policy Office Horioka)

Foreign price survey

**Nov.** Statement of industry opinion at the Central Social Insurance Medical Council

**Jan. R4** Collaboration plan working-level meeting (planned)

- Cost-effectiveness evaluation
- Institutional subcommittee activities
- JFMDA various committee activities
- Monthly meeting



# (D) 2022 monthly meeting, representative meeting holding plan

Time: From 2:30 pm to 5:00 pm

Location: Siemens Healthineers 5th floor meeting room (in principle)

## Schedule:

January 20<sup>th</sup> (Thu)

February 24<sup>th</sup> (Thu)

March 24<sup>th</sup> (Thu)

April 21<sup>st</sup> (Thu)

May 26<sup>th</sup> (Thu)

June 23<sup>rd</sup> (Thu)

July 21<sup>st</sup> (Thu)

August 25<sup>th</sup> (Thu) + information exchange meeting

September 15<sup>th</sup> (Thu)

October 20<sup>th</sup> (Thu)

November 17<sup>th</sup> (Thu)

December 08<sup>th</sup> (Thu) representative meeting + information exchange meeting

# (R) 2021 accounting report

## 2022 March forecast

	2021 budget	2021 Nov. result	vs. budget	Expected costs incurred by 2022 Mar.	2022 Mar. FC	FC vs. budget
Previous year carryforward	¥10,155,586					
Membership fee	¥5,600,000	¥6,000,000	107.1%	¥0	¥6,000,000	107.1%
Info. exchange meeting participation fee	¥300,000	¥0	0.0%	¥0	¥0	0.0%
Others (miscellaneous income such as interest)	¥0	¥45	#DIV/0!	¥0	¥45	#DIV/0!
Total income this year 2021	¥5,900,000	¥6,000,045	101.7%	¥0	<b>¥6,000,045</b>	101.7%
Total income	¥16,055,586					
Secretariat operating expenses (personnel expenses)	¥3,400,000	¥2,067,266	60.8%	¥1,000,000	¥3,067,266	90.2%
Representative meeting & info. exchange meeting	¥800,000	¥0	0.0%	¥0	¥0	0.0%
JFMDA membership fee	¥600,000	¥600,000	100.0%	¥0	¥600,000	100.0%
Survey / translation costs	¥600,000	¥118,462	19.7%	¥0	¥118,462	19.7%
Secretariat activities	¥80,000	¥11,830	14.8%	¥10,000	¥21,830	27.3%
Subcommittees, TF activities	¥400,000	¥0	0.0%	¥150,000	¥150,000	37.5%
HP maintenance cost	¥0	¥26,267	#DIV/0!	¥0	¥26,267	#DIV/0!
Others (miscellaneous expenses)	¥20,000	¥5,104	25.5%	¥10,000	¥15,104	75.5%
Total spending	¥5,900,000	¥2,828,929	47.9%	¥1,170,000	<b>¥3,998,929</b>	67.8%
Income and expenditure settlement in this year					<b>¥2,001,116</b>	
This year's carryforward					¥12,156,702	

# (D) 2022 budget (draft)

	2021 budget	2022 Mar. FC	vs. budget	2022 budget draft	FC vs. budget
Previous year carryforward	¥10,155,586			¥12,156,702	
Membership fee (20万円/社x29)	¥5,600,000	¥6,000,000	107.1%	¥5,800,000	103.6%
Info. exchange meeting participation fee	¥300,000	¥0	0.0%	¥300,000	100.0%
Others (miscellaneous income such as interest)	¥0	¥45	#DIV/0!	¥0	#DIV/0!
Total income	¥5,900,000	¥6,000,045	101.7%	<b>¥6,100,000</b>	103.4%
Total income	¥16,055,586			¥18,256,702	113.7%
Secretariat operating expenses (personnel expenses)	¥3,400,000	¥3,067,266	90.2%	¥3,400,000	110.8%
Representative meeting & info. exchange meeting	¥800,000	¥0	0.0%	¥800,000	#DIV/0!
JFMDA membership fee	¥600,000	¥600,000	100.0%	¥600,000	100.0%
Survey / translation costs	¥600,000	¥118,462	19.7%	¥600,000	506.5%
Secretariat activities	¥80,000	¥21,830	27.3%	¥80,000	366.5%
Subcommittee, TF activities	¥400,000	¥150,000	37.5%	¥400,000	266.7%
HP maintenance cost	¥0	¥26,267	#DIV/0!	¥30,000	114.2%
Others (miscellaneous expenses)	¥20,000	¥15,104	75.5%	¥20,000	132.4%
Total spending	¥5,900,000	¥3,998,929	67.8%	<b>¥5,930,000</b>	148.3%
Income and expenditure settlement		¥2,001,116		¥170,000	
This year's carryforward		¥12,156,702		¥12,326,702	