



한국의료기기산업협회

Korea **M**edical **D**evices **I**ndustry **A**ssociation

Myung Jung Kim, Vice Chairman
KMDIA

Korea's leading and reliable association for competitive medical device companies

01

Introduction

02

Organization

03

Major Responsibilities of KMDIA

04

Activities of the committee

Vision

**Korea's leading and reliable association
for competitive medical device companies**

Mission

**Development of
MD Industry**

**Enhancement of
Healthcare Technology**

Growth of MD Market

Strategy

01

Establishing fundamental infrastructure
for the growth of MD industry

02

Formulating regulatory framework
for the MD industry

03

Forming a cooperative network
within MD industry

04

Facilitating high-valued MD industry
and supporting export of MD

05

Establishing a fair trade
environment in supply of MD

06

Promoting global cooperation
and regulatory harmonization

Advanced KMDIA with constant challenges and efforts

1999

07.08

Establishment of Korea Medical Devices Association

2001

11.29

Changing the name to Korea medical Devices Industry Association

2002

03.14

Co-hosting KIMES

03.26

Commissioned as an organization of Statistic reports of Korean MD market

2005

07.18

Designated as GMP education center

2007

01.01

Designated as Pre-review organization for MD advertisements

2011

10.11

Joined GMTA

2015

02.05

Designated as an execution organization for international medical devices exhibitions

2017

12.28

Joined APACMED

2019

04.24

Built 'IMDRF Supporting Team' in KMDIA

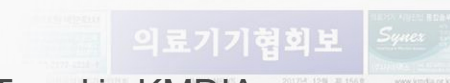
2020

01.14

Joined DITTA

11.17

Hosted 'Korea IMDRF Working Groups' General Meeting



산업혁명 첨단의료기기 개발 위해 정부 지원 절실
지난달 24일, 정부-산업계 '2017 의료기기 토크콘서트' 개최

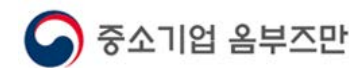


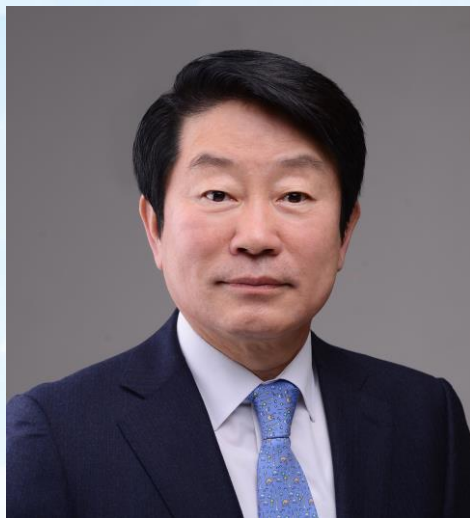
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International (MOU Signing)



Domestic (MOU Signing)

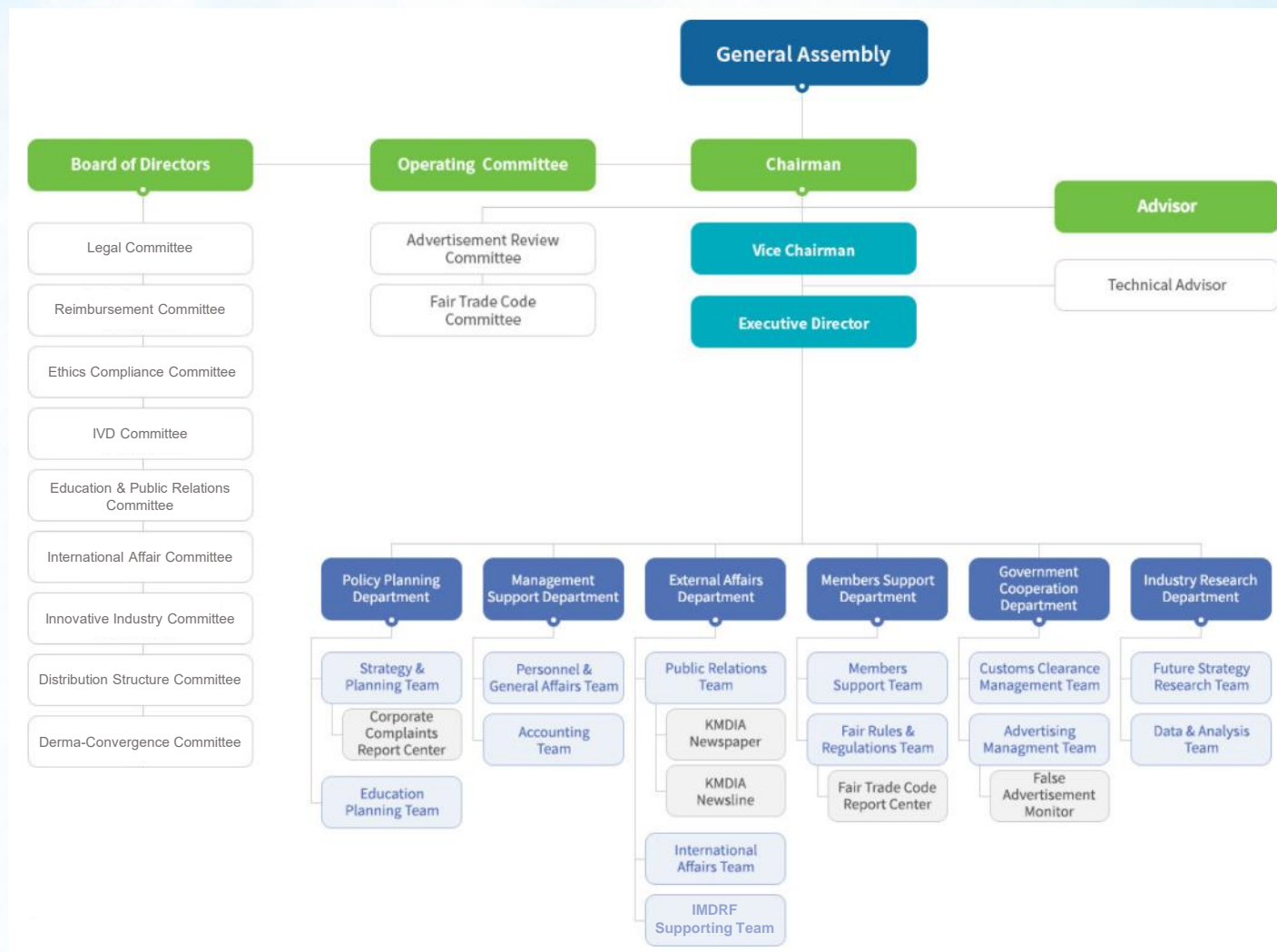




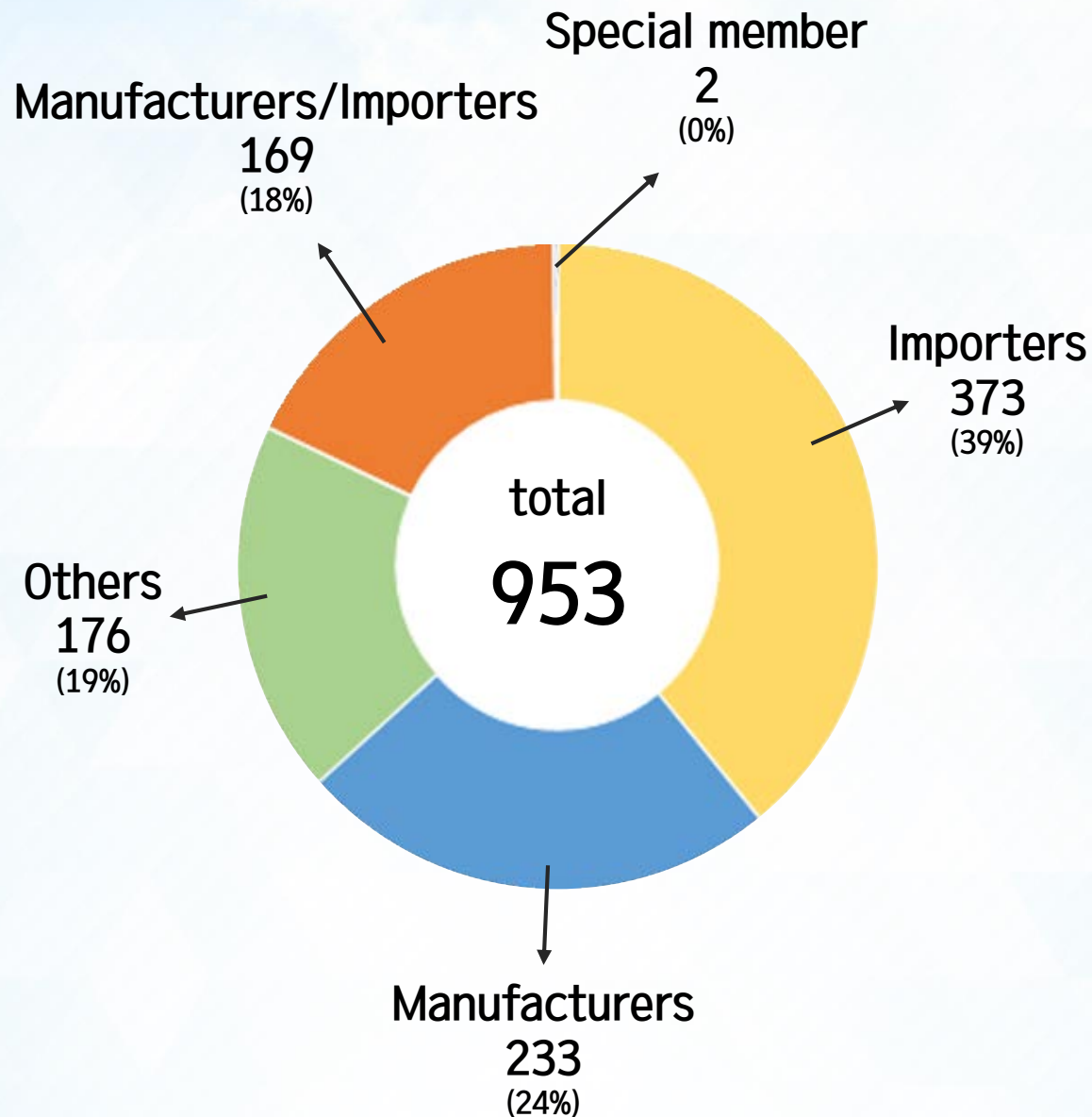
Korea Medical Device Industry Association

Chairman **CHEOL WOOK YOO**

“
We will keep our best to develop
medical devices industry for growth
in MD market to become the world's
top seven MD powers by 2021
”



Membership Status



(As of 2021.02.19)

Market Share of Member Companies in The Korean Market (2019, USD)



Korea's Top 5 Export and Import Item (2019)

Top 5 Export Items

1. Ultrasound Imaging System
2. Implant Fixture(endosseous)
3. Biomaterial Graft/Prosthesis
4. Soft Contact Lens(daily-wear)
5. IVD Reagents for Self-testing II

Top 5 Import Items

1. Soft Contact Lens(daily-wear)
2. CT System
3. MRI System
4. Coronary Artery Stent
5. Multifocal Intraocular Lens

Major Responsibilities of KMDIA

03 | Major Responsibilities



01 Membership Support



02 Regulations & Reimbursement Policy Support

03 PR, Media support

04 Industry policy support

05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review

06 Ethics, Public service support

07 General Affairs, Budget, Human Resources

1

Supporting MD Industry and solving of a pending issue of members

- Cooperating with the government and related organizations
- Researching the current issues and proposing alternatives and regulations

2

Training programs for MD human resources

- Fostering professional MD manpower through practical education programs
 - Complimentary education by CHAMP (Government support business)
- * CHAMP : Consortium for Human Resources Development Ability Magnified Program

3

Networking with Overseas MD Associations

- Interacting with foreign organizations such as GMTA, APACMED...etc.
- Supporting for international regulatory harmonization and global expansion

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4

IMDRF Supporting team

* IMDRF : International Medical Devices Regulators Forum

- Cooperation with MFDS
 - To assist MFDS with its IMDRF roles and responsibilities
- IMDRF Working Groups Assistance
 - To operate and manage Korea IMDRF Working Groups
- External Relations
 - To conduct external relations with IMDRF member countries and their related organizations



02 Regulations & Reimbursement Policy Support



01 | Membership support

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1

Proposing improved regulations for membership

- Supporting consultative groups to improve regulatory system
- Finding corporations' complaints and proposing improvements to the government

2

Gathering industries' opinions about legislative/ Administrative guidelines

- Suggesting revised proposals by reflecting field opinions

3

Gathering and distributing major MD-related issues and industrial support information

- Holding policy forum, workshop and panel discussion with government officials
- Delivering opinions and proposing alternatives through CEO meeting

03 PR, Media support



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1

Introducing the activities of KMDIA and member companies

- Issuing press releases and on-offline newspapers

2

Communicating industry's perspectives on major healthcare issues to the news media and general public

- Initiative activities (ex. Press conference)

3

Publishing KMDIA newspaper and Newsline(online)

- Free distribution of 5,200 copies monthly
- Newsletter and mobile newspaper service

의료기기협회보

“대금결제기한 규정 및 공급내역보고 전가 금지”
서정숙 의원 ‘특수 관계 거래 제한’ 법 개정안 발의



(의료기기업 일가계업협회에서 제1차 전문위원회의 발의)
1. 판매자가 환자 의료기기 구매 계약 체결 전 전문위원회의 심의 결과에 따라
2. 판매자가 의료기기 구매 계약 체결 후, 구매 계약 체결 전 전문위원회의 심의 결과에 따라
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04 Industry Policy Research



01 | Membership support

02 | Regulations & Reimbursement Policy Support

03 | PR, Media support

05 | Customs clearance, Statistic report of Korean MD market, Advertisement pre-review

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07 | General Affairs, Budget, Human Resources

1

Strengthening competitiveness of MD industry

- Data analysis on statistic reports of Korean MD market
- Publication of an yearbook of MD industry's statistics

2

Proposing new policies throughout research and networking

- Performing research project for the development of MD industry
- Supporting for interconnected networks between domestic and global companies

3

Supporting R&D of the Cutting-edge MD

- Operating the 4th Industrial Revolution Medical Devices Special Committee
- Holding Medical Devices Industry Awards
- Protecting the Intellectual Property Rights

05

**Customs clearance,
Statistic report of
Korean MD market,
Advertisement
pre-review**



01 | Membership support

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1

Issuing Standard Customs Clearance Reports

- Reviewing and issuing standard customs clearance reports to protect danger caused by importing MD

2

Issuing Requirement Exemption Import Certification

- Issuing requirement exemption import certification to medical devices exempted from submitting standard customs clearance reports

3

Statistic report of Korean MD market

- Gathering the statistic data on production, exports, imports and repairs of Korean MD market

4

Medical Devices Advertisement pre-review

- Preventing customers' damages caused by false and exaggerated advertisements and providing the information for appropriate use

06 Ethics, Public Service Support



01 | Membership support

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1

Improving distribution environment of MD

- Enacting and conducting the 'Fair Trade Code' of medical device

2

Strengthening MD management ethics

- Providing an institutional framework for the fair distribution environment
- Providing 'Fair Pay Med' system

3

Promoting social contribution activities with membership

- Free health examination service for the vulnerable

4

Conducting a campaign for safe use of MD

- Distributing the safety usage of life-friendly medical devices

07

General affairs, Budget, HRM



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1

Support and management of the overall operation

- General affairs, Accounting, Computerizing and Human Resources management

2

Support of the board of directors and general meeting

- Holding the board of directors and general meeting
- Follow-up on decisions

3

Enactment and amendment of the articles of association

- Enactment and revision of internal guidances

01 Legal Committee

- ▶ Improving regulatory system of MD
- ▶ Proposing improved regulations for membership
- ▶ Promotion of MD industry environment

02 Reimbursement Committee

- ▶ Proposal of improved reimbursement regulations
- ▶ Development of health policy for industry
- ▶ Research and analysis of reimbursement policy

03 Ethics Compliance Committee

- ▶ Improving fair distribution environment
- ▶ Disputing over conflicts within industry
- ▶ Discussion over Fair Trade Code and specific standards

04 IVD Committee

- ▶ Proposal of improved IVD regulations
- ▶ Research and analysis of reimbursement policy for IVD
- ▶ Improvement of new health technology assessment



05 Education & Public Relations Committee

- ▶ Introduction of new laws and regulations of MD
- ▶ Improvement of MD environment
- ▶ Introduction of the activities of KMDIA & member companies
- ▶ Fostering human resource through training programs
- ▶ Development and review for new education programs
- ▶ Consulting on improved educational programs



06 International Affair Committee

- ▶ Research & Analysis for overseas MD market
- ▶ MOU signing with international organizations
- ▶ Information sharing on global MD market
- ▶ Networking with Foreign embassy



07 Innovative Industry Committee

- ▶ Business support of venture and start-up
- ▶ Cooperation with competitive corporations for global market
- ▶ Commercialization of MD connected to technical R&D business
- ▶ DB building about domestic MD technologies



08 Distribution Structure Committee

- ▶ Distributing GMP obtained medical devices
- ▶ Improving medical devices distribution structure
- ▶ Ensuring fair distribution system



09 Derma-Convergence Committee

- ▶ Proposing policy and improving regulations of medical aesthetic device
- ▶ Building data base on medical aesthetic device industry
- ▶ Cooperation with related agencies and academic



Location



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Gangnam-gu, Seoul, South Korea, 06173





Thank you

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