Myung Jung Kim, Vice Chairman
KMDIA

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

**Vision**

**Development of MD Industry**

**Enhancement of Healthcare Technology**

**Growth of MD Market**

**Mission**

**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
Establishment of Korea Medical Devices Association

Changing the name to Korea medical Devices Industry Association

Co-hosting KIMES
Commissioned as an organization of Statistic reports of Korean MD market

Designated as GMP education center

Designated as Pre-review organization for MD advertisements

Joined GMTA

Designated as an execution organization for international medical devices exhibitions

 Joined APACMED

Built ‘IMDRF Supporting Team’ in KMDIA

Joined DITTA

Hosted ‘Korea IMDRF Working Groups’ General Meeting
# Domestic & International Partners

## International (MOU Signing)

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<th>International Organization</th>
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<tr>
<td>AdvaMed</td>
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<td>JFMDA</td>
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<td>JIRA</td>
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<td>AIMEC</td>
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<td>CMC</td>
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<td>Federation of Israeli Chambers of Commerce</td>
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<td>SRI International</td>
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<td>Nawaloka Hospitals PLC</td>
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## Domestic (MOU Signing)

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<td>Kamia</td>
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<td>KBIO HEALTH</td>
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<td>NIDS</td>
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<td>Gachon University Gil Medical Center</td>
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<td>KU-IRI</td>
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<td>National Cancer Center</td>
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<td>Chungbuk University</td>
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<td>Daegu Mobile Internet Development Association</td>
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Organization

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”
Current State of KMDIA

Membership Status

- Manufacturers/Importers: 169 (18%)
- Importers: 373 (39%)
- Others: 176 (19%)
- Manufacturers: 233 (24%)
- Special member: 2 (0%)

Total: 953

(As of 2021.02.19)
Market Share of Member Companies in The Korean Market (2019, USD)

- **Production**: 72%
- **Export**: 55%
- **Import**: 85%

**KIMDA Members**

- Production: 4.85 billion
- Export: 2.06 billion
- Import: 3.55 billion

Korean Market Size

- Production: 6.69 billion
- Export: 3.71 billion
- Import: 4.16 billion

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

01 Membership Support

02 Regulations & Reimbursement Policy Support

03 Public Relations

04 Industry Policy Research

05 Customs Clearance, Statistic Report of Korean MD market, Advertisement Pre-review

06 Ethics, Public Service Support

07 General Affairs, Budget, Human Resources
Major Responsibilities of KMDIA

01 Membership Support

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

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
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
Major Responsibilities of KMDIA

02 Regulations & Reimbursement Policy Support

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

01 Membership 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
03 PR, Media support

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
Major Responsibilities of KMDIA

04 Industry Policy Research

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

01 Membership support
02 Regulations & Reimbursement Policy Support
03 PR, Media support
05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review
06 Ethics, Public service support
07 General Affairs, Budget, Human Resources
05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review

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
Major Responsibilities of KMDIA

06 Ethics, Public Service Support

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

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 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
Activities of the Committee

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
Activities of the Committee

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
Activities of the Committee

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
1, 3F Hanjin Bldg., 6, Teheran-ro 103-gil, Gangnam-gu, Seoul, South Korea, 06173
Thank you

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