www.mfds.go.kr/eng

Your Vision, Our Future
Korean Medical Device

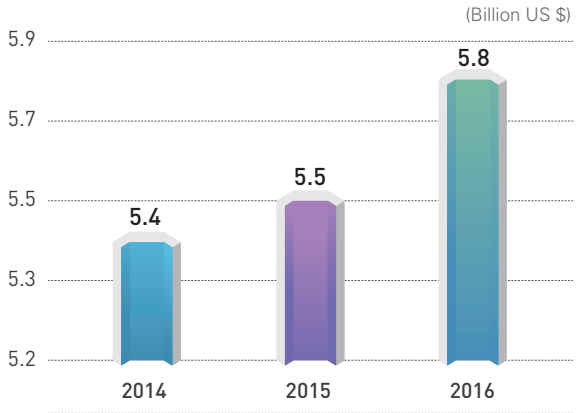
Ministry of Food and
Drug Safety

01.

Passion for Growth & Excellence

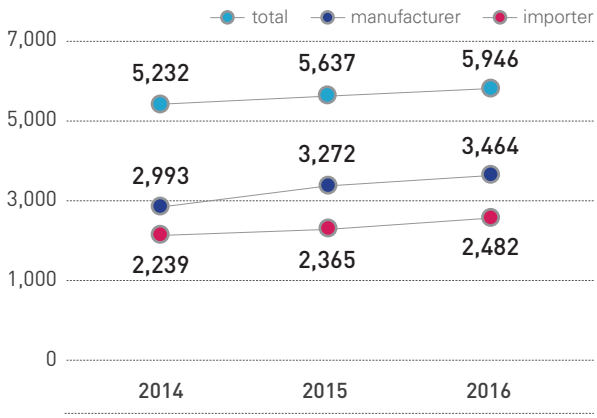
With a 5% average annual growth rate, the Korean medical device market was valued at approximately US$ 5.8 billion in 2016, making it the 9th largest market in the world.

Korean MD Market Size



The World Medical Markets Factbook 2016

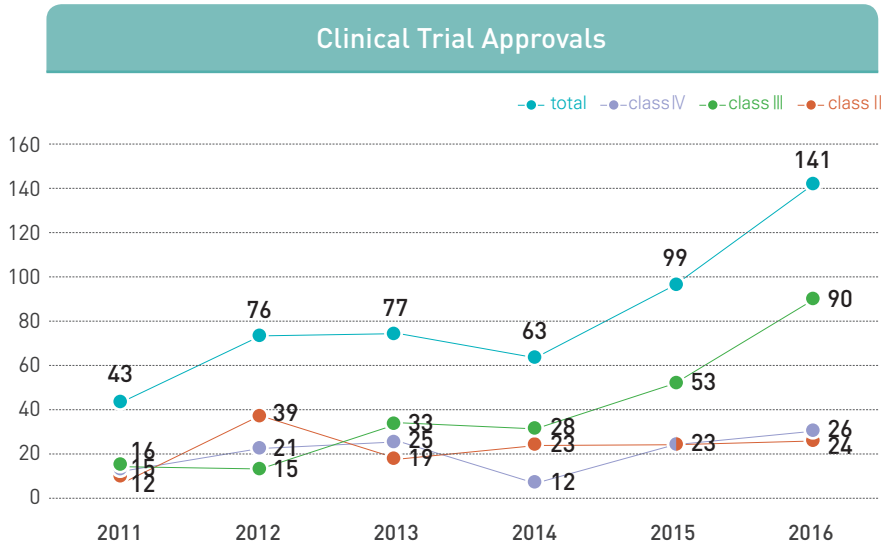
Korean MD Companies



Major Exports of Korean Medical Devices in 2016

Ranking	Top 10 Exports
1	Ultrasound Imaging System
2	Dental Implant
3	Soft Contact Lens
4	Biomaterial Graft/Prosthesis
5	Medical Image Processing System
6	IVD Reagents for Testing of the Immune System
7	Probe for Medical Use
8	IVD Reagents for Infectious Disease
9	Laser Surgical Unit
10	X-ray System

Based on ISO 14155 and due to expedited processing for clinical trials, diverse clinical researches are conducted in Korea.



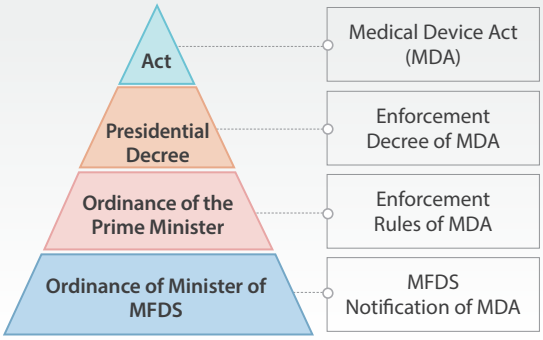
There are a total of 153 clinical trial centers designated by Ministry of Food Drug Safety (MFDS), ensuring good clinical trial environments.

02.

Internationally Harmonized Medical Device Regulatory System

Korea comprehensively regulates medical devices with a well-organized legal system and clearly defined regulations.

Medical Device Regulations



Overall MD Regulatory System and its Operation

- **Developed regulatory system by legislating Medical Device Act in 2003**
- **Established risk-based Medical Device Classifications in 2003**
  - –I~IV Classes based on GHTF/IMDRF principles
  - –Designation of 2,225 items
- **Introduced QMS for medical device in 2004**
  - –Harmonized with ISO 13485
- **Established Clinical trial for medical devices in 2005**
  - –Harmonized with ISO 14155

MFDS has an efficient and well-balanced system to manage the total lifecycle of medical devices.

Overall Medical Device Regulations			Tasks	
Pre-Market	QMS Conformity		Conformity Assessment	Manufacturing (Class II to IV) Importing (Class II to IV)
	Business License		Approval of business license for manufacturing and importing	
	Clinical Trial		Approval for Clinical Trial Plan (If required)	
	Marketing Authorization	Notification (class I)	Notifications of Item (immediately notified at the submission of application) ※ Exemption of QMS inspection	
		Certification - Approval (Class II to IV)	Certification	Class II
			Approval	Class III & IV
Distribution	Selling-Renting-Repairing		Listing for Selling, Renting & Repairing Businesses	
Post-Market	Post-Market Safety Management		Re-Certification of QMS conformity	
			Management of Labeling and Advertising	
			Adverse Event Reporting	
			Recall	
			Tracking of High Risk Medical Devices	
			Enforcement Actions (Fines/Restitutions, etc)	

03.

Strategic Operation based on Expertise & Efficacy

With a systematic organizational structure, MFDS is strategically operated for an effective medical device management.

[Total : **315** employees]

Medical Device Safety Bureau

Divisions

- Medical Device Policy Division
- Medical Device Management Division
- Medical Device Safety Evaluation Division

Main Tasks

- Establishing medical device-related policies
- Establishing QMS Standards of Manufacturing site
- Processing and tracing management information on safety including adverse events

Medical Device Evaluation & Research Department

Divisions

- High-tech Medical Devices Division
- Cardiovascular Devices Division
- Orthopedic & Restorative Devices Division
- Dental & Gastroenterology Devices Division
- In Vitro Diagnostic Device Division
- Medical Device Research Division

Main Tasks

- Medical device approval
- Supporting innovative medical device approval
- Training technical document review agencies

6 Regional Branches

Divisions

- Seoul Regional Office of MFDS
- Busan Regional Office of MFDS
- Gyeongin Regional Office of MFDS
- Daegu Regional Office of MFDS
- Gwangju Regional Office of MFDS
- Daejeon Regional Office of MFDS

Main Tasks

- QMS audit
- Issue of business license
- Post-market surveilance

MFDS works cooperatively with other third party organizations to increase efficiency and expertise.

[Total : about **1,552** experts]

Affiliated Organization

Medical Device Information & Technology Assistance Center (MDITAC)

A legal entity established in 2012

-Supports and provides with information regarding clinical trials, standards, safety, training, etc.
-Issues Notification of Class I devices & Certification of Class II devices

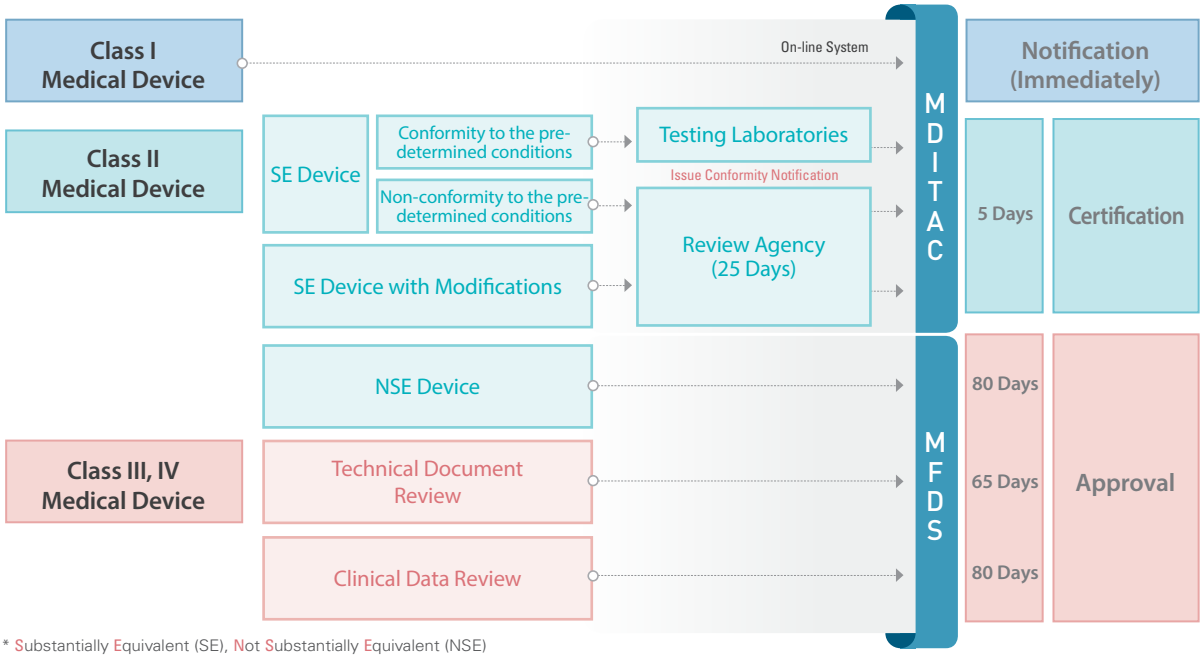
Related Organizations designated by MFDS

Medical Device Testing Laboratories	**Test medical devices (16 Labs)**
Medical Device QMS Audit Institutions	**Conduct QMS audit and issue certificates with MFDS (4 Institutions)**
Technical Document Review Agencies	**Review technical documents on class II devices (7 Agencies)**
Medical Device Clinical Trial Centers	**Hospitals designated by MFDS (153 Centers)** **Conduct clinical trials for medical devices**

04.

Predictable Approval System with Scientific Approach

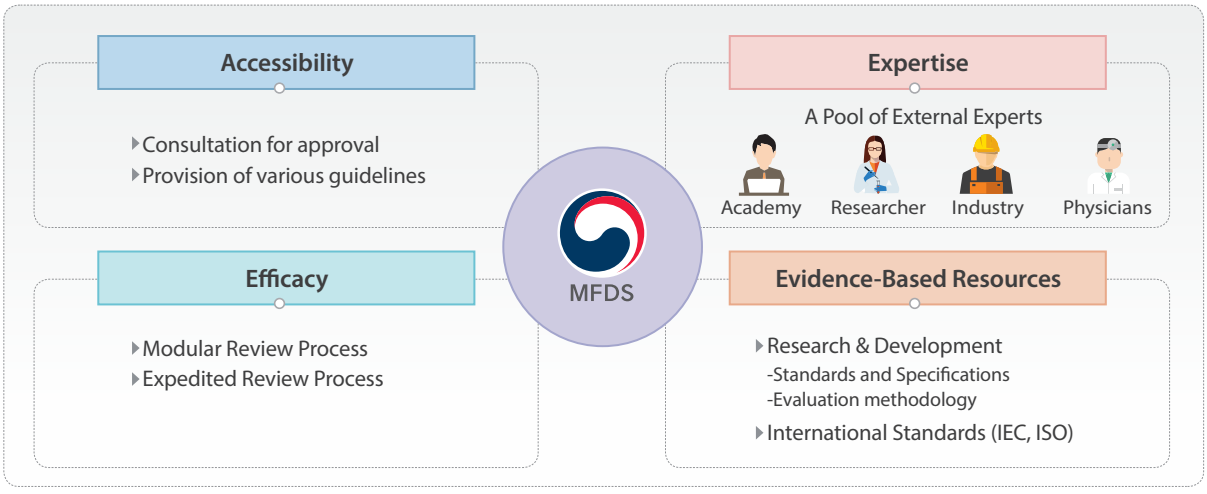
Based on risk classification of medical devices, each classes of devices have different pathways for a marketing authorization.



* Substantially Equivalent (SE), Not Substantially Equivalent (NSE)
* Medical Device Information and Technology Assistance Center

For an easy access and better compliance of regulations, MFDS provides consultations and various guidelines for applicants.

MFDS also gains additional scientific understanding from a pool of external experts as needed, and invests on various R&D projects to increase expertise in review and approval processes.

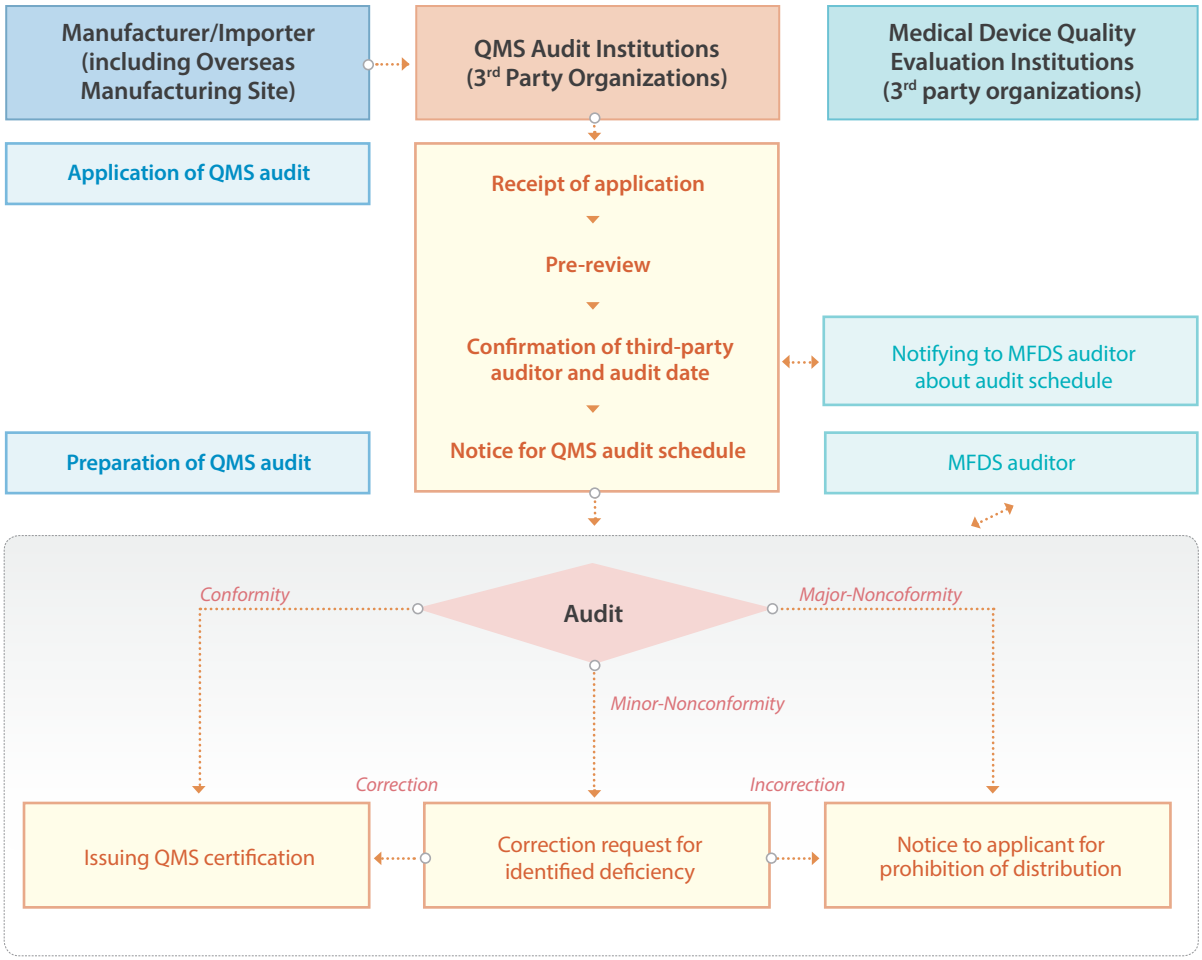


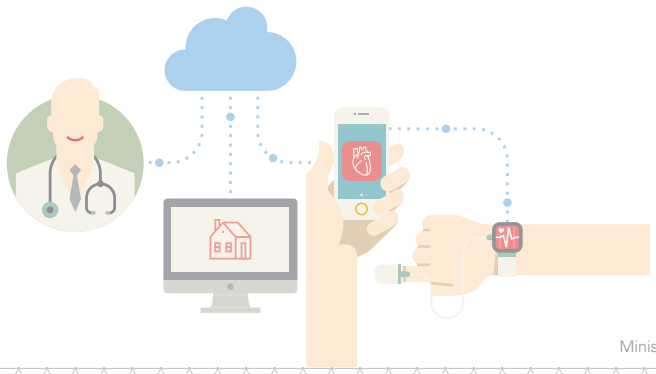
05.

Emphasis on Quality : QMS

- Korean QMS is harmonized with the international standard, ISO 13485.

- QMS Audit Procedures for Medical Device





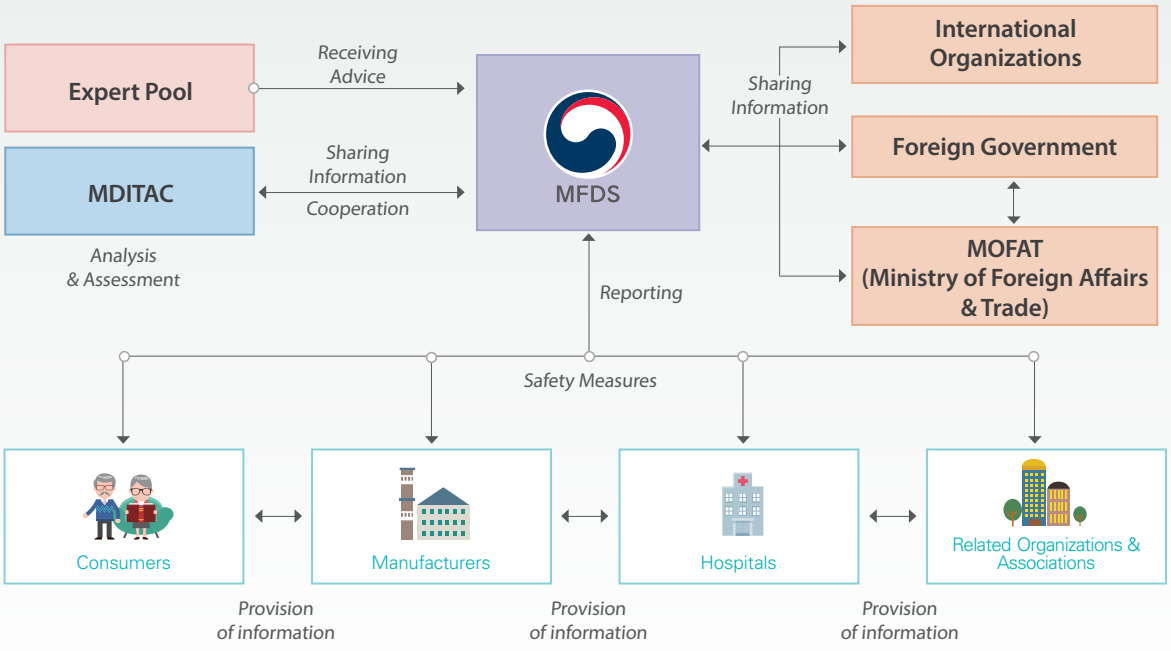
06.

Adverse Event Reporting

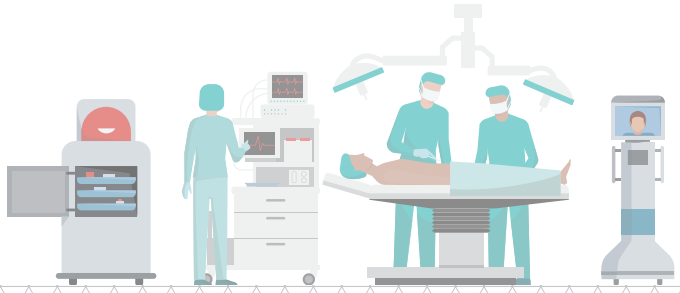
Medical device manufacturers, importers and distributors are required to report any adverse events and keep those records.

- Life-threatening adverse events should be reported within 7 days, with additional report to be submitted within 8 days after the initial report.
- Other non-life-threatening adverse events should be reported within 30 days.

Medical Device Adverse Event Reporting and Management System



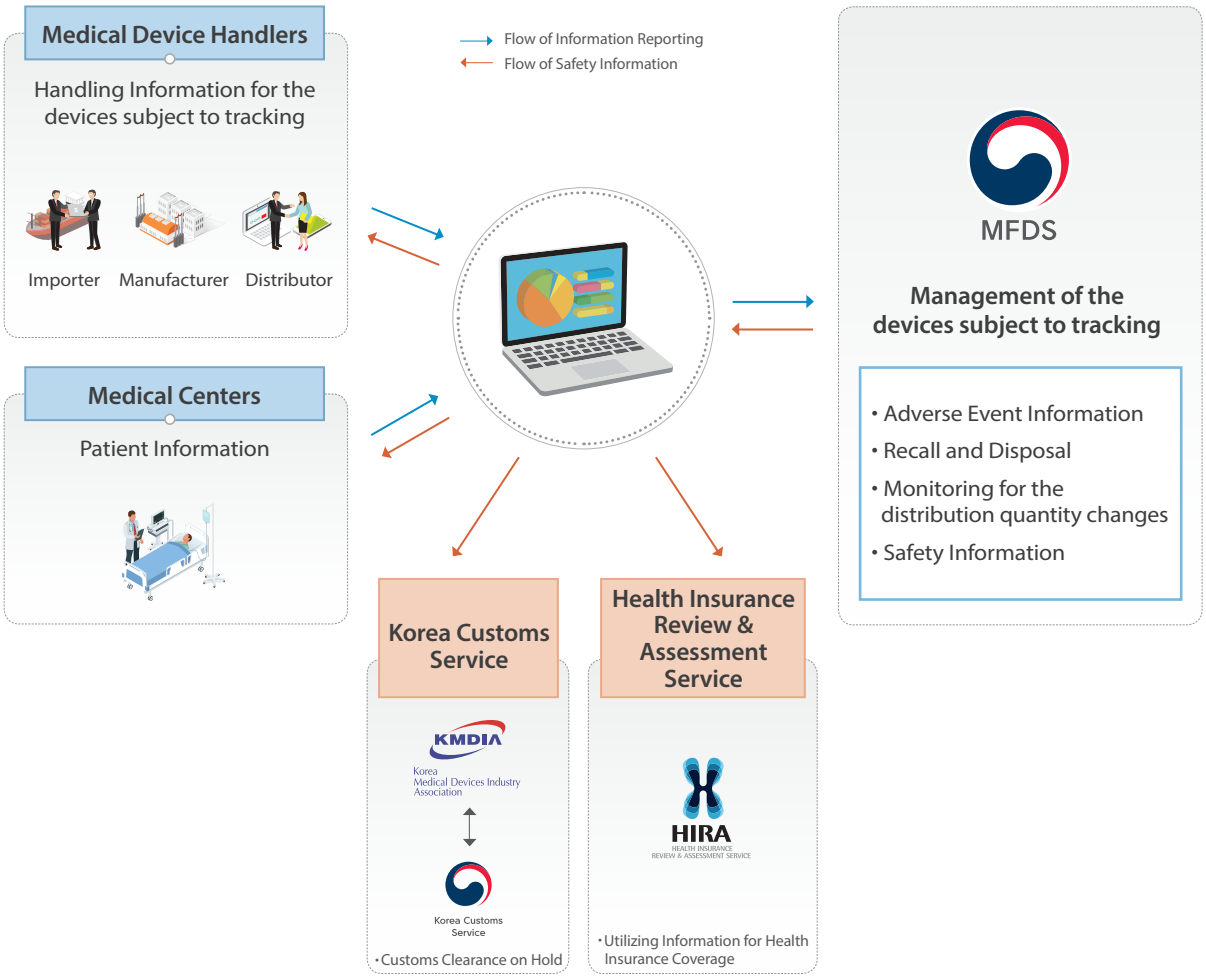
- All of collected information regarding adverse event reports are being reviewed and analyzed to be used for field safety corrective actions.



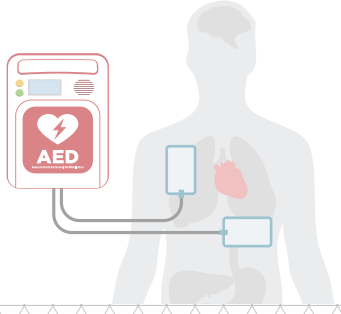
07.

Monitoring & Tracking System

MFDS has designated 52 implantable and life-supporting medical devices, which are subject to tracking for patient safety.



MFDS collects information about devices and patients from manufacturers and importers to regulate the safe use of those devices and prevent medical incidents.



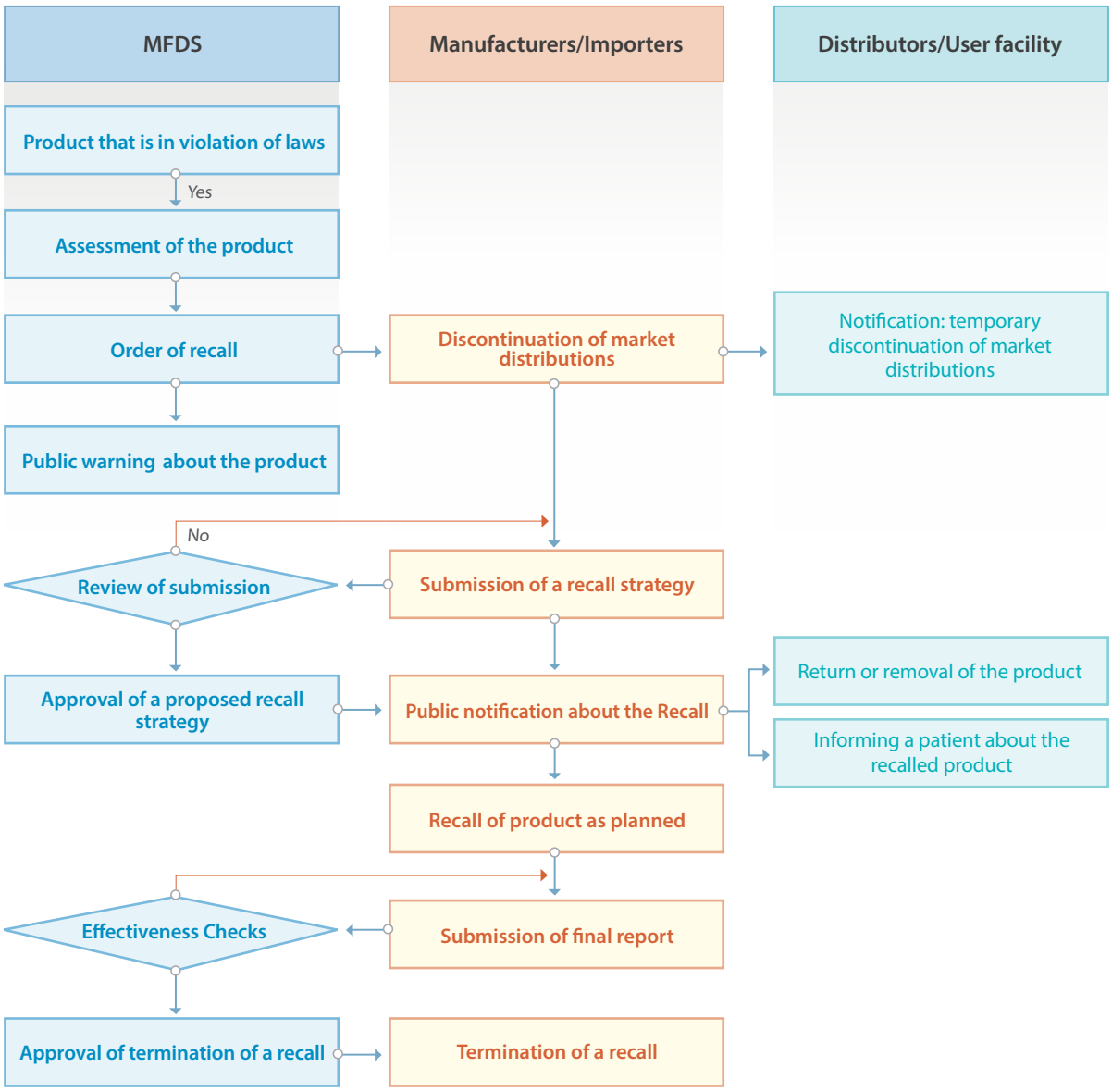
08.

Recalls

Types of Recall

- (**Firm-initiated Recall**) Recall made voluntarily by the firm after the discovery of safety issues or product defects that may have potential health risk to patients.
- (**Government-initiated Recall**) Recall order made by Minister of MFDS when the product is determined to be defective or potentially harmful.

Procedure for Government-initiated Recall



09.

Sustainable Effort & Commitment for International Cooperation

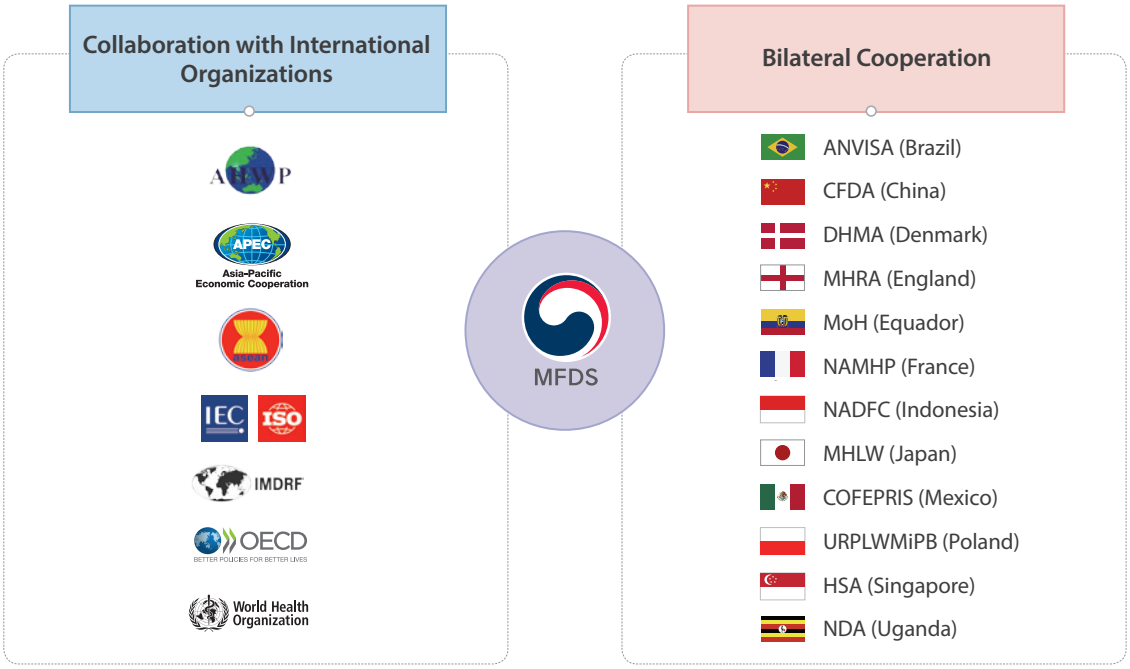
Asian Harmonization Working Party (AHWP)

▸ MFDS, as a chair of AHWP, takes a leading role among 30 member economies from Asia, Middle east, South America and Africa
-Publishes various AHWP guidelines for implementation in pre- and post-market management of medical devices.
-Provides Capacity Building workshops for low and middle income countries.

International Medical Device Regulators Forum (IMDRF)

▸ MFDS actively participates and cooperates with IMDRF working groups and the committee members.
▸ Member countries : EU, US, Canada, Japan, Australia, China, Russia, Brazil and Singapore

International Cooperation Activities



Ministry of Food and
Drug Safety

Medical Device Evaluation Department I Cardiovascular Devices Division
Contact : md1mfds@korea.kr
Published in 2017 (Ver.1)

187, Osongsaengmyeong 2-ro, Osong-eup, Heungdeok-gu, Cheongju-si,
Chungcheongbuk-do, Republic of Korea 28159
www.mfds.go.kr/eng