

Post-COVID19

Medical Device Business in South Korea: Challenges & Opportunities for U.S. Firms

April 9, 2021



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Synex Consulting: Who we are

Descriptions	Features
Business	One-Stop Shop for Healthcare Market Access into South Korea
Established	April 2002
Employees	130 employees
Expertise	Healthcare Market Entry Issues
Customer Industry	Medical device In-vitro diagnostics Pharmaceuticals Biopharmaceuticals
Service Sectors	Regulatory Affairs Reimbursement Approval Quality Management System Certification Clinical Research (CRO) Market Research Distribution
URL	www.synex.co.kr



Objectives

- **15-min snapshot**
 - What COVID19 has changed in the medical device market in South Korea
 - New regulatory and market access opportunities for medical devices suppliers

Quick Updates: Korea as Healthcare Market



Korea in East Asia 2021

- **Third largest population***
 - 51 million
 - cf. China (1.4 billion), Japan (126 million)
- **Second wealthiest country****
 - GDP per capita 2020: US\$31,838
 - cf. Japan US\$ 40,246
- **One of the fastest aging countries in OECD countries**
 - 65+ population: 8.5 million or 16% in 2020; up to 25% until 2030



* UN statistics 2019

** IMF 2019

Healthcare Payer Characteristics

- **Single national public payer operated by central government**
 - National Health Insurance (NHI)
- **NHI: universal healthcare system**
 - Mandatory coverage for all citizens and healthcare providers
- **Supplementary private healthcare insurance providers**
 - Around 84% of population* has annual subscriptions with a private payer
 - Standard policies and premiums are provided by government



* Korean Statistical Information Service (KOSIS) 2018

Healthcare Service Providers as Medical Device Business Customers

Type	Numbers
General Hospital	356
Hospital	1,486
Long-term Care Hospital	1,468
Clinic	32,441
Total	35,751

* Korean Statistical Information Service (KOSIS) 2019

Medical Device Market

- **US\$7.8 billion (2019)**
 - 3rd largest market in Asia
 - 10th largest market in the World
- **Imported devices supply 62% of the market**

Korea Device Market

(US\$ millions, %)

Descriptions	2015	2016	2017	2018	2019	CAGR %	Remarks
Market Size	5,265	5,873	6,197	6,817	7,803	10.4	
Domestic Production (A)	5,001	5,603	5,823	6,511	7,279	9.9	58% of market
Export (B)	3,067	3,386	3,578	3,972	4,324	9.0	
Import (C)	3,331	3,657	3,952	4,279	4,849	9.9	62% of market

World Device Market Ranks

Ranks	Countries	US\$ 100 Million	World Market Share
1	USA	1,729	42.8%
2	Japan	289	7.2%
3	Germany	285	7.1%
4	China	273	6.8%
5	France	154	3.8%
6	UK	120	3.0%
7	Italy	102	2.5%
8	Canada	71	1.8%
9	Spain	70	1.7%
10	Korea	65	1.6%

*Market Size = Domestic production (A) – Export (B) + Import (C)

*Source: Korea Medical Device Industry Association (KMDIA)

<https://www.kmdia.or.kr/KO/document/center/center01.asp>

Korea in COVID19 Pandemic

- **One of the largest and best-organised epidemic control programs in the world**

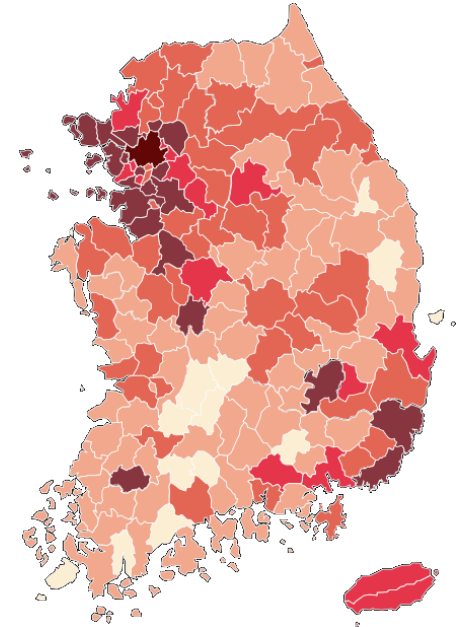
- Korea Disease Control & Prevention Agency (KDCA)'s fast and transparent response to pandemic
- Extensive and rapid testing
- People's good compliance to hygiene and gathering control policies



- **One of the least impacted countries by corona pandemic**

As of April 8, 2021

- Infection rate: 0.2%
- 10.7k confirmed cases
- 1,756 deaths



Medical Device Industry in Pandemic

- **Fast supply of test kits and various devices**
 - First COVID19 test kit approved in 15 days of the first confirmation of infection
 - A total of 310 test kits approved for domestic or global supply
- **Rising public awareness of importance of healthcare technology industry**
 - MFDS as regulatory authorities for gatekeeper for supply of safe devices
 - Medical device industry as supplier of life-saving products, such as, diagnostic kit, thermometers, face masks, ventilators, syringes, etc.

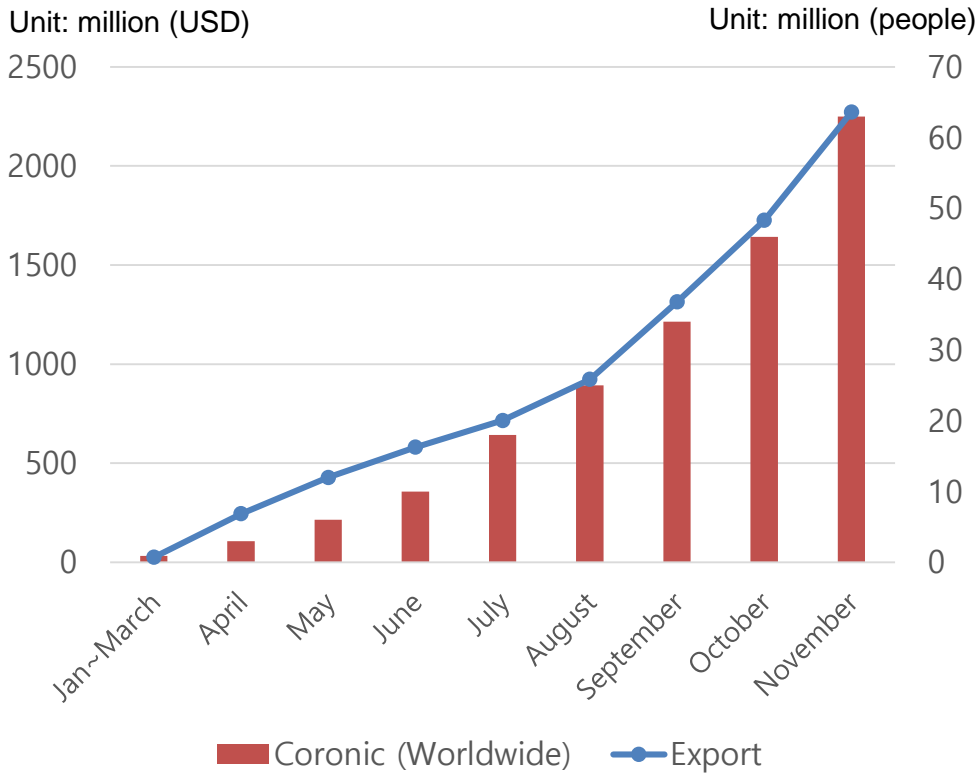
MFDS Approvals for COVID19 Test Kits

Categorization		Approval	
EUA(Molecular)		16	
Market authorization	Molecular	12	18
	Antigen -Antibody	6	
Medical devices for export only	Molecular	121	276
	Antigen -Antibody	155	
Total		310	

* Source: Ministry of Food & Drug Safety (MFDS)

Contribution to Global Pandemic Response

Korea Exports of COVID19 Diagnostic Reagent & Related Goods (accumulated, 2020)



Export of COVID19 related items (Jan- Aug, 2019 VS 2020)

Unit: million (USD)

Item	2019	2020	Growth%
Diagnostic Device	894.3	2,224.9	148.8%
Mask	123.9	522.1	321.4%
Hand Sanitizers	4.3	248.2	5,672.1%
PPE	83.9	188.5	124.7%
Others (thermometer, respirator)	55.4	119.5	115.7%

*Korea Customs Service & Ministry of Food and Drug Safety

*Korea Customs Service

Momentum to Accelerate Digital Transformation for Contactless Society

- **“Digital New Deal Policy** to invest US\$2.2 billion on the Digital New Deal including digital health platform in 2020, with additional funds to come in future annual budgets.”
- **“National AI Strategy** to bolster the development of AI domestically. The strategy set the goal of becoming the world’s third most competitive digital economy by 2030.”

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South Korea’s Digital New Deal

South Korea aims to establish a foundation for core fields of the future: 5G, big data, and AI.



By [Troy Stangarone](#)

June 25, 2020

As the world continues to recover from the COVID-19 induced economic recession, the Moon administration has proposed spending [76 trillion won \(\\$62 billion\)](#) over the next five years on the Korean New Deal to prepare the South Korean economy for the future.

<https://thediplomat.com/2020/06/south-koreas-digital-new-deal/>

Regulatory Changes for Medical Devices



Korea's long-term ambition to become a medtech developing country

Biohealth National Vision Annoucement (2019, May)

Remarks by President Moon Jae-in at Biohealth National Vision Proclamation Ceremony (9th Stop of Nationwide Economic Tour: Chungcheongbuk-do Province)

May 22, 2019

Share



President Moon proclaimed Vision 2030 to promote Pharmaceuticals and Medical Device industry accomplishing the following goals:

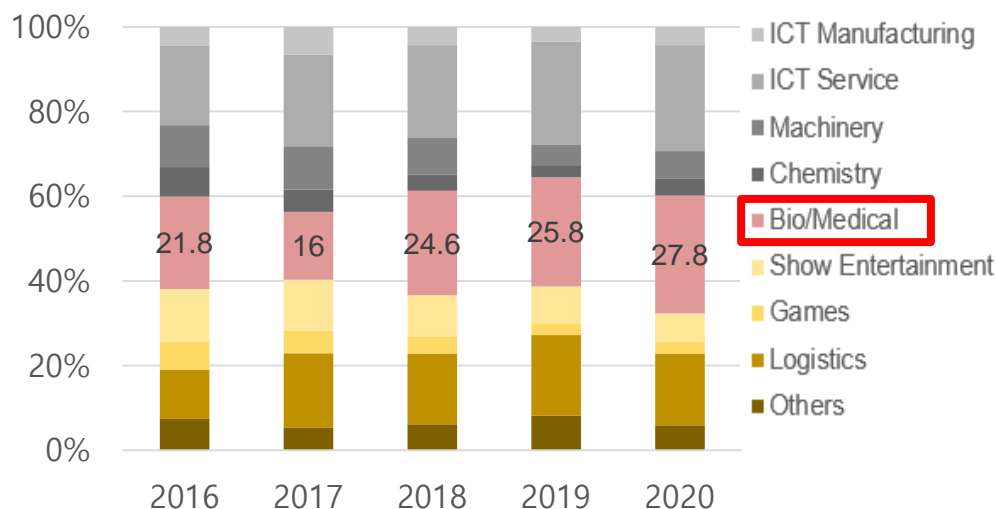
- Increase global market share to 6%
- \$50 billion Export
- Designation of the industry as TOP 5 major export industry
- Increase the government funding to more than 4 trillion won (annually) until 2025
- Establishment of effective regulatory landscape for medtech

Increasing Venture Capital Investment to Healthcare Technology Innovation

- US\$1 billion invested in 2019 for medtech innovation
- Account for the biggest proportion for the most of recent 5 years

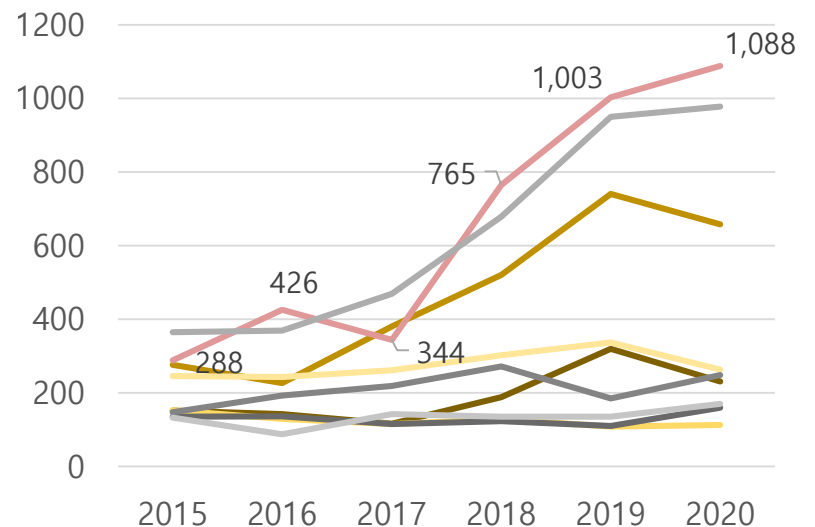
New Investment Proportion by Industry

(Unit: %)



New Investment Amount by Industry

(Unit: US\$ millions)



*Source: KOREAN VENTURE CAPITAL ASSOCIATION

Regulators' Lessons Learned from the COVID19 pandemic

- **Senior MFDS official's recent comments**
 - Dr. Hong, Choong-man, Director, High-tech Medical Device Division, MFDS, International Medical Device Regulators' Forum (IMDRF), March 16, 2021
 - “COVID19 redefined the role of medical device regulators in public health crisis, one of which is [assurance of safety and just-in-time supply](#). We also reaffirmed the [importance of cooperation with stakeholders including manufacturers](#), labs and other governments.”

New legislations to support development of new medtech

- **Act to Nurture Medical Device Industry and to Support Innovative Medical Devices (May 1, 2020)**

- Designation of Innovative Medical Device Designation
- Designation of Innovative Medical Devices
- Modular Review
- Pre-application Consultation
- Fast Track Review

In-Vitro Diagnostics Act (May 1, 2020)

- Parallel Review for Companion Diagnostics (CDx)
- Lab Certification for lab-developed Testing (LDT)
- Designation of Clinical Performance test labs
- Introduction of Good Clinical Practice (GCP) for clinical performance testing

MFDS Regulatory Initiatives

New MFDS Offices

- Digital Health Device
- Pre-submission Consultation Division
- Expedited Review Division of Drugs and Medical Devices

New Guidelines

- Digital Therapeutics (DTx)(Aug 2020)
- Artificial Intelligence and Big Data-based Medical Devices (Nov 2020)
- Cybersecurity of Medical Devices (Nov 2020)
- Innovative Software as a Medical Device (Aug 2020)

MOHW Faster Market Access Initiatives

- **Health Technology Assessment (HTA) Deregulation Measures**
 - Designation of Innovative health technology
 - 3-5 years for in-market evidence development
 - Grace period for New Health Technology Assessment
 - 1 year in-market HTA exemption
 - First-Market/After Evaluation HTA for IVD
 - Designation of research-stage technology
 - In-market evidence development at patient charge

New Pricing Scheme

- **Reference pricing scheme for expensive service and medical devices**
 - April 1, 2021

Takehome Messages



Takehome Messages



- **Good news**

- Korea is a passionate technology innovation country.
- Healthcare innovation is one of the national growth strategies.
- Funds for technology innovation are plentiful.
- The earliest technology adopting population is more than ready to take more quality of life
- Regulatory system for medical product approval is transparent and well harmonized with international practices
- Government is ready to help better healthcare technologies for earlier patient access
- Public healthcare insurance program benefits the entire population and covers more cost-effective technology

Takehome Messages



- **Challenges to foreign innovators**
 - Korea has its own pain points in its healthcare system, such as, concerns about rapidly mounting healthcare costs. Immerse yourself and take part of it.
 - Find your business sustainability within the healthcare system in Korea. Sometimes you need a government approval even if you want to introduce your products without government insurance coverage.
 - Language and cultural differences are significant in business. Try to read between lines to catch up subtle contexts and perspectives in relationships with business partners or government agencies.
 - As a rule of thumb, good partnership with in-country companies is most important.



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Thank You

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