Department for Business & Trade

SOUTH KOREAN MARKET INTELLIGENCE REPORT 2023

Digital Health

GREAT
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01 INTRODUCTION

South Korea (Korea) offers strong opportunities for UK digital health companies as the market is growing rapidly due to investments and support from medical institutions, conglomerates, start-ups, and the government. In recent years, Korea is placing ever more focus on digital health as it embraces digitization more broadly across its economy. The country is in the process of building out a smart medical infrastructure with the aim of tackling issues such as a sustained rise in medical costs, increased chronic disease and an aging population. The regulatory and commercial framework have been established to enable Korea's digital health market to flourish and this makes it an attractive market for UK companies to target.

Korea's digital health market has shown strong and consistent growth in recent years; worth an estimated GBP 3.1bn in 2021 the market is expected to grow at 8.1% CAGR for the next few years[i]. The government is actively supporting the industry, and the smart healthcare products and services market is ripe with opportunity. Recent regulatory changes and proposals have signaled a positive outlook for the Korean market, but some hurdles remain due to barriers around data sharing and telemedicine, of which companies need to be aware.

Former President Moon Jae-In and his administration identified digital health as a key growth sector on taking office in 2017, pledging to increase investment and review restrictive regulations to spur innovation in the digital health sector. Under the 'Korean New Deal', the government established plans to promote the development of key technologies related to digital health, including artificial intelligence (AI), big data, and blockchain, as well as to spend GBP 130mn to build a smart medical infrastructure[ii]. The government also announced measures to help ease Korea's strict data management rules.

Current President Seok-Yeol Yoon looks set to continue along the same path in digital healthcare. He has promised to implement a digital health counselling system and use real time health monitoring combined with big data analysis to help Korea prepare to become a super-aged society. In addition, he pledged to expand pilot projects on telemedicine services for underserved populations and promote an innovative medical system through the creation of digital hospitals[iii].

Korea's conglomerates are also investing in digital health and collaborating internationally. Samsung Electronics has been conducting digital health research and focusing on developing platforms for preventable medicine and innovative medical devices, as well as the development of health functions on its existing wearable products and apps.

Areas of interest for UK digital health companies include health information technologies (HIT), big data including precision medicine and AI-based healthcare solutions, blockchain, telemedicine and consumer health electronics. As the government and private sector continue to develop the local digital health market through investments and R&D initiatives, opportunities for companies in the UK to do business in Korea will also grow.

02

KOREA: AN OVERVIEW

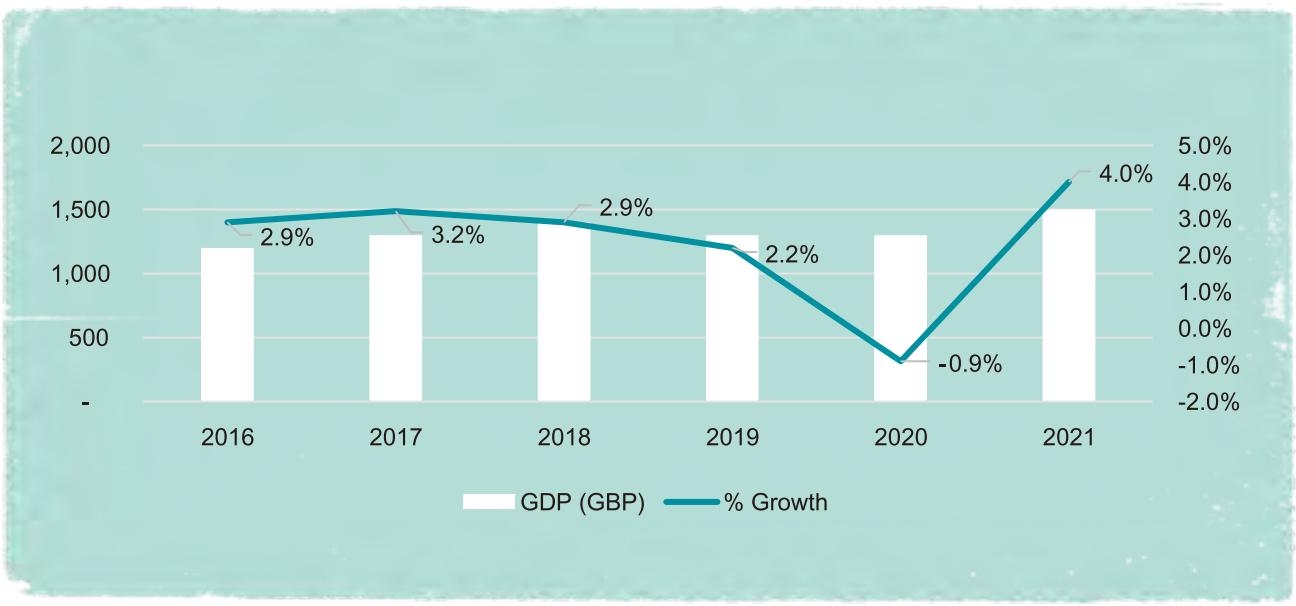
KEY POINTS

- Korea is an economically advanced country and a leader in developing cutting-edge technologies
- It is the world's 10th largest economy with a GDP of approximately GBP 1.45 trillion[iv]
- Korea's GDP growth rate is forecast to be around 2.7% for 2022 and 2.0% for 2023[iii]

In the space of just 60 years, Korea has transitioned from an agricultural economy to one driven by high-value industries such as automotive, shipbuilding and advanced manufacturing. Perhaps most remarkable of all is the country's success in the areas of electronics and information communications. As well as dominating the global semiconductor industry, Korea has leap-frogged its peers in terms of ICT infrastructure (smartphone penetration rate, broadband speed, etc.) and this fact, coupled with a demanding and technology-embracing population, means Korea is becoming an economy driven by creativity and innovation.

With a population of 52 million, Korea boasts the 10th largest economy in the world, a GDP of GBP 1.45 trillion and a per capita GDP of GBP 25,760 in 2021[iii]. Trade accounts for over 63% of Korea's GDP and its economic performance is heavily affected by the economies of China, the US and Japan[v]. Trade and investment between Korea and the UK have grown rapidly as a result of the FTA that came into effect in 2011 and Korea sees the UK market as one way to lessen its dependence on the US and China markets. The fallout from the COVID-19 pandemic caused Korea's GDP to decline -0.9% in 2020. However, having handled the pandemic relatively well, the country's growth rate is expected to rebound, and the economy is forecast to grow 2.7% for 2022 and 2.0% for 2023[iii].

Figure 1: Korea GDP (2016-2021)



Unit = GBP 1bn / Source: World Bank[iii]

KOREA'S HEALTHCARE SYSTEM

Korea's healthcare system is funded by the compulsory National Health Insurance Service (NHIS) that covers 97% of the population and administered by the Ministry of Health and Welfare (MoHW)[vi]. As of 2021, Korea boasts approximately 97,000 medical institutions including advanced and general hospitals, clinics, nursing homes, and traditional Korean medical institutions[v]. As half of the population in Korea is located in Seoul and Gyeonggido which surrounds Seoul, nearly half of these institutions are located in the region. This has led to the Korean healthcare industry being heavily Seoul-centric.

In Korea, hospitals are categorized as non-profit organizations but are run as businesses. Hospitals compete to attract patients and are highly receptive to new technologies. The healthcare industry is dominated by a handful of advanced, large players that operate networks of branch hospitals. The top 5 mega hospitals which command approximately 5% of all outpatients visits nationwide are as follows: Asan Medical Center, Samsung Medical Center, Seoul National University Hospital, Severance Hospital and St Mary's Hospital. These hospitals, known as 'the Big 5' are all located in Seoul, and each has around 2,000 beds and approximately 1,000 doctors[vi].

Despite the Big 5 all being located in Seoul, 61% of visiting patients come from outside of the city, making the hospitals a top destination for people living in other regions of the country seeking quality outpatient care[vii]. Korea's well-developed network of high-speed trains make access to the capital possible within just a few hours for most of the country which helps facilitate the grouping of top medical centers in Seoul.

As of 2021, there is a total of 703,468 hospital beds in Korea for a population of 52 million[vii]. This translates to 13.6 hospital beds for every 1,000 people, placing it first in the world in terms of bed-to-population ratio[vii]. Korea is home to many hospitals of significant scale, as just 40 large public hospitals account for approximately 46,200 of its hospital beds[viii].

Korea is a receptive market for new healthcare solutions and the small number of very large hospitals which are all located in the Seoul metropolitan area combined with Korea's advanced ICT structure helps to boost this integration. Innovative UK digital healthcare businesses will find Korea to be an ideal test bed with many opportunities for new digital healthcare applications.

03

DIGITAL HEALTH MARKET OVERVIEW

KEY POINTS

- Korea's digital health market reached GBP 3.1bn in 2021 with growth of 8.1% per year expected in coming years[i]
- Investment in digital health is viewed as key to maintaining costs with a rapidly aging population
- Some key digital health market players include Samsung Electronics, LG Electronics, KT, Vuno, Lunit and the 'Big 5' hospitals

Korea's digital health market was estimated to be worth GBP 3.1bn in 2021 and is expected to continue to grow at a steady rate[i]. Nonetheless, Korea is also facing health and social issues due to an increase in chronic disease and a substantial increase in public medical expenditure. Korea's medical cost growth has been increasing steadily in recent years hitting as high as 8% year on year growth in 2019, part of this can be attributed to increasing demand for fixed amounts of labor in the industry[ix].

Korea is also growing older – over 20% of its population is expected to be over 65 by 2026[x]. This issue is one of the key drivers of the Korean government's interest in building an eco-system and infrastructure for digital health which it views as one part of the solution. Additionally, as part of its plan to drive growth in the fourth industrial revolution, the government has set up a special committee for digital health to develop ways to apply new technologies and medical data to improve public health.

The digital health market in Korea can be divided into five main areas: health information technologies (HIT), healthcare big data including precision medicine and AI-based healthcare solutions, blockchain-based healthcare technologies, telemedicine, and consumer health electronics. Improvements in the quality of healthcare services and adoption of the exchange of medical data throughout the country have been gained through developments in the HIT and big data sectors. Additionally, in the push for development of smart healthcare infrastructure, consumer health electronics and blockchain technology are seeing significant interest.

Prior to the COVID-19 pandemic, telemedicine programs were allowed only on a limited basis, such as pilot projects, due to strict government regulations. However, there has been a push from interest groups towards deregulation, giving hope to new opportunities. During the pandemic, Korea saw the temporary implementation of telemedicine as a measure to limit face-to-face contact and decrease the transmission of the virus. Despite a positive reception from patients and doctors the temporary administrative order allowing for telemedicine expired when the government implemented its 'living with COVID-19' strategy, but with further proposals being reviewed by the National Assembly, telemedicine appears to have a more promising future than it did before the pandemic.

Korea's digital health market has become active in recent years, with more products and solutions being developed locally as companies increase their R&D efforts. The market is still growing, and hospitals are interested in testing new technologies, but companies may face challenges with commercialization due to Korea's rigid reimbursement system. Nonetheless, I think Korea is an attractive market to use as a testbed for product development.

Soo-Yong Shin, Associate Professor, Department of Digital Health – Sungkyunkwan University

KEY PLAYERS

The digital healthcare ecosystem in Korea is made up primarily of corporations, medical institutions, R&D centers, start-ups, and government institutions. Large hospitals such as Seoul National University Hospital and Samsung Medical center are driving digital health initiatives while many of the corporate players are global brands like Samsung Electronics and LG. Relevant government bodies are responsible for creating regulations and approval processes for digital health solutions and products include the Ministry of Health and Welfare (MoHW) and the Ministry of Food and Drug Safety (MFDS). Korea's burgeoning start-up scene is also playing an ever-increasing role and includes digital health success stories like Lunit and InBody.

Figure 2: Digital Health Ecosystem

Korea's famous conglomerates such as Samsung Electronics are investing in developing innovative digital healthcare products for sale at home and abroad. Samsung's wearable products, Galaxy Watch 4 and Galaxy Fit 2, are popular sellers in the consumer electronics market and come with apps to allow users to track their fitness and overall health. Samsung's medical affiliates Samsung Medison and Samsung SDS are creating digital medical equipment and health analytics solutions which utilize big data, AI and other new technologies.

Telecommunication companies such as SK Telecom and KT oversee the development of the mobile networks and ICT infrastructures needed to implement digital health solutions.

SK Telecom, for example, entered into a strategic partnership with GE Healthcare in September 2021 to develop a digital health infrastructure utilizing each company's know-how to build fast data networks and create advanced digital health products[xi]. KT signed agreements with ICU-grade biosensor developer Sibel Health (US) in November 2020 and with bioelectronics developer NeuroSigma (US) in June 2021 to boost its standing in the digital health market[xii xiii].

Healthcare solution providers are developing systems which help medical institutions achieve their digitization goals. One example is ezCaretech which is Korea's largest EMR/EHR systems provider and has its solutions, such as BESTcare, implemented in

Table 1: Major Players in Digital Health

Corporations	2021 Revenue	Solutions	Remarks
Samsung Electronics	GBP 208bn	Galaxy Watch, Samsung Health	Wearable products and mobile apps for health and fitness tracking
LG Electronics	GBP 57.6bn	14HK701G-W	Digital X-ray detector using AI imaging software
KT Corp	GBP 18.4bn	AI-based healthcare kiosk	Measures health data such as blood pressure, heart rate, body fat, etc. linked to smart phones
SK Telecom	GBP 12.3bn	AI Care	Senior care service for elderly homes provided through SKT's AI speaker product, Nugu
Samsung SDS	GBP 8.4bn	S-Patch Cardio	Wearable ECG monitoring device and cloud-based analytics solution
Samsung Medison	GBP 0.25bn	GR40CW	Digital radiography system
ezCaretech	GBP 0.04bn	BESTcare	EMR and EHR systems

Source: Intralink Research

major hospitals throughout Korea, including Seoul National University Hospital, as well as in hospitals overseas. Many Korean start-ups look to expand overseas quickly after proving their technology in the domestic market and ezCaretech is doing this partnering with large corporations. It partnered with LG Electronics to develop a telemedicine solution for overseas markets, called ezOntheCall, that combines ezCaretech's EMR-based applications with LG's video conferencing technologies.

Korea is becoming a hotbed for all kinds of technology-based start-ups and digital health is no exception. Lunit is often recognized as Korea's most successful digital health start-up company to date, develops AI-based precision diagnostic solutions, such as its INSIGHT series, which utilizes AI to analyze chest X-rays and mammography images to detect lung diseases and several cancers. Personal health coaching start-up Noom raised GBP 47mn in 2022 from US-based investors like Sequoia Capital and Serena Ventures[xiv]. InBody has gone from a successful start-up to a medium size company with revenues from their easy-to-use body composition analysis machines growing from GPB 31mn in 2014 to nearly GPB 90mn in 2021[xv]. Huray Positive is another interesting Korean start-up providing self-management services for people with kidney disease and having raised over USD 16m in funding from local venture capital funds[x].

Table 2: Notable Digital Health Start-ups

Start-ups	Products	Remarks
LifeSemantics	LifeRecord	AI-based PHR platform
Lunit	INSIGHT CXR	AI solution analyzing chest X-rays to detect lung diseases
InBody	InBody 970	Body composition analyzer measuring muscle mass, body fat ratio,
Noom	Noom (Weight)	Personalized diet and exercise coaching app
Huray Positive	HID	Self-management services for kidney disease management
Exosystems	exoRehab	Wearable medical device for patients suffering from musculoskeletal disorders or undergoing neurorehabilitation
MediHere	DoctorHere	Telemedicine platform for Koreans residing in the US to receive medical services from Korean hospitals
Vuno	Med-DeepBrain	AI medical device for brain analysis to diagnose neurodegenerative diseases

Source: Intralink Research

The Big 5 Hospitals

Hospitals have been exceptionally active through internal efforts in digitizing information, building internal Big Data systems, and introducing AI solutions through their own initiatives. The 'Big 5' have become leaders in the digitization of Korea's healthcare system, largely driven by the need to meet better care standards as a responsibility for servicing around 5% of all patients in the country[vi]. Given their large size and the fact that many medical association leaders in Korea are also practicing physicians or head researchers at these institutions they exert a strong influence on the medical sector as a whole. UK digital healthcare companies will want to partner with these institutions for testing their technologies in Korea to speed up their adoption.

Table 3: Korea's 'Big 5' Hospitals

Hospital	No. of beds	Daily no. of outpatients	Daily no. of inpatients
Asan Medical Center	2,715	11,680	2,427
Severance Hospital	2,437	6,850	2,300
Samsung Medical Center	1,989	5,823	253
Seoul National University Hospital	1,761	6,132	1,497
Seoul St. Mary's Hospital	1,374	4,663	1,205

Source: Korea Biomedical Review, Big-5 hospitals dominate patient care[vi]

*Additional information on the Big 5 hospitals can be found in Appendix A

04

KEY AREAS IN DIGITAL HEALTH

KEY POINTS

- The Korean government is investing heavily to support both R&D and the provision of new digital health products to its citizens, helping drive the industry forward

- Key opportunity areas include:
  - HIT: Medical imaging systems, HIE solutions, clinical trial management systems
  - Big Data: Precision medicine platforms and AI-based medical devices and solutions
  - Blockchain-based medical record database and disease prediction services
  - Wearable consumer health electronics for diagnostics, monitoring and disease prevention

HEALTH INFORMATION TECHNOLOGIES (HIT)

The Korean government has encouraged a wide adoption of HIT, such as universal EHR/EMR, to help improve nationwide delivery of healthcare and promote the development of the domestic healthcare industry. Korea is a highly digitized society and healthcare organizations are no exception viewing HIT as a natural evolution of their industry. According to a 2020 MoHW report, 100% of all tertiary hospitals in Korea use EMR systems, while the utilization rate for general hospitals is 95.8% and 90.5% for small hospitals (100 beds or less)[v].

Korea's adoption of EMR systems is higher than the OECD average of 93%, and these high utilization rates have helped nearly completely digitize patient data, digital storage of clinical images, electronic hospital administration databases and the expanding use of remote sensor technology[xvi]. The use of healthcare information exchanges is one area for improvement among Korean institutions, highlighting the need for healthcare ICT standardization. As of 2020, the HIE utilization rate was 78.6% for tertiary hospitals, 39.8% for general hospitals, and 18.7% for small hospitals[v]. Utilization rates for other types of HIT solutions can be found in the following table.

Table 4: Utilization Rates of HIT Solutions, by Hospital Type

Solution Type	Tertiary Hospitals	General Hospitals	Small Hospitals
Electronic Medical Record	100%	95.8%	90.5%
Picture Archiving & Communication System	100%	97.4%	87.3%
Laboratory Information System	97.6%	76.5%	35.8%
Health Information Exchange	78.6%	39.8%	18.7%
Mobile EMR	45.2%	21.9%	10.1%

Source: 2020 MoHW Report on Digitization of Korea's Healthcare Industry[v]

HIT market leaders include ezCaretech, Korea's leading provider for healthcare information management systems and developers of the BESTCare solution that is widely used at many tertiary hospitals. Companies such as Samsung SDS and LG CNS are also leading providers of management systems. In many industries in Korea, internal development of digital systems is common, and some hospitals have developed their own internal solutions.

Korea is also actively working to improve HIE rates both between and within organizations. To encourage hospitals to share information with other healthcare providers the Korean government created the FEEDER-NET system in 2018[xvii]. The system converts participating hospitals' EHR data into a common data module (CDM) and makes it available via a cloud-based open research platform. As of November 2021, 84 organizations have been integrated into the network[xviii].

In 2021, Korean tech conglomerate Naver Corporation which operates Korea's largest search engine announced plans to enter the digital healthcare. Using its advanced IT technologies and AI capabilities, the company plans to develop solutions to integrate and manage medical data. Also, in February 2021, the Ministry of Health and Welfare (MoHW) launched the My HealthWay platform, a new PHR system giving patients greater accessibility and control over their health data. The system currently provides integrated management of medical check-up data, prescription data, and vaccination data, with the end goal of having all medical and health records accessible in a single location.

The Korean government is developing a framework for the integration of data within the health sector, bridging the gap between medical institutions and individual patients. The My HealthWay platform was created for this purpose and once fully developed, will provide patients greater access to their hospital medical data and hospitals access to an individual's personal health data. Eventually, patients will have ownership of all their health data, meaning companies will have to implement business models that are not only hospital-centric but also patient-centric to be successful.

Se Young Jung, Assistant Professor, Healthcare ICT Research Center – Seoul National University Bundang Hospital (SNUBH)

Korea's view towards patient ownership of data indicates that there will be greater openness and opportunities for companies in the future.

Opportunities

Despite Korea's high usage of EMR systems in medical institutions and very high utilization of HIEs in large hospitals, smaller hospitals have much lower usage rates which presents a market opportunity for solutions providers. However, there are several reasons that this market opportunity may be difficult to take advantage of. One challenge that companies may face is regulations around the sharing of patient data as current laws do not allow for the transfer of patient information to third parties without explicit consent. The previous and current presidential administrations have promised to loosen data regulations, but this has proven difficult to accomplish so far. Industry experts also expect to see the standardization of health records, which in turn, will help foster further digitization of hospitals.

There are other opportunities for UK companies with mobile HIT solutions as this is an area of focus in Korea. Tertiary hospitals only utilize mobile EMR systems at a rate of approximately 45% according to the MoHW[v]. However, over the next three years this rate is expected to double[v]. Smaller hospitals are also expected to adopt mobile EMR systems to remain competitive in the market[v].

Advancements in clinical trial research programs are leading to a need for better management systems at hospitals. Usage of digital therapeutics and other recent developments in new medicines and treatment programs means the management of clinical trial data has become an important focus for Korean organizations. Furthermore, the MFDS requires clinical trial documentation to be submitted for review where research procedures and data integrity are carefully examined. Thus, it has become vital for hospitals and R&D institutions to implement organized clinical trial management systems.

The government is also actively carrying out its plans to develop smart medical infrastructure based on digital technology. As outlined in the Korean New Deal, the government is targeting the creation of 18 smart hospitals by 2025 to allow for the real-time monitoring, diagnosis and treatment of patients[xix]. In addition, President Seok-Yeol Yoon's campaign pledged to implement a digital health counselling system which would manage patient medical data and digital health services[xx]. This means hospitals will need to implement HIT solutions to fully digitize operations, providing opportunities for UK companies.

The high level of digitization in health data in Korea and the UK means Korea is an ideal market for UK companies as complicated adjustments or data aggregation are not needed. Korea's high level of use of digital technologies as well as the well-developed ICT infrastructure helps make the case that this is an excellent market for UK companies in this sector.

HEALTHCARE BIG DATA

Korea's current administration is making strong efforts to utilize big data and related applications such as precision medicine and AI solutions. In August 2018, former President Jae-In Moon's government announced the investment of GBP 688mn to develop better data technology and revise data regulations, and since 2020, the government has been releasing medical big data for companies to use to develop medical solutions[xxi]. Current President Seok-Yeol Yoon has pledged to continue along the same path using big data and real-time health monitoring to create a preventative healthcare system which would help Korea prepare for a rapidly aging population.

The Big 5 Korean hospitals are leading the way in R&D efforts for big data in the healthcare sector. Seoul National University Hospital established its Medical Big Data Research Center in 2018 as an ICT research center for building a medical big data platform and creating the foundation for the convergence of research between universities, hospitals, and companies. After the government amended regulations which allowed digital hospital records to be stored on external servers, cloud-based systems started becoming more common. The Precision-Hospital Information System (P-HIS), a Korea University Medical Center led consortium of hospitals and companies, enables big data analysis of patient results while supporting the development of precision medicine and healthcare AI.

Precision Medicine

Korea began developing precision medicine programs in 2017 and this continues to be an area of focus for the country. The general population understands the value of such programs and is positive about seeing such programs implemented. A large survey conducted by researchers from Yonsei University and the National Institute of Health (NIH) found that a majority of respondents supported precision medicine programs and had a positive attitude toward providing personal data for research purposes.

In April 2021, the city of Ulsan and the Ulsan National Institute of Science and Technology (UNIST) announced the completion of their joint 10,000 Genome Project, successfully mapping the genome sequence of 10,000 individuals which was begun in 2015[xxii]. The project is expected to help drive the growth of this industry in Ulsan which has special regulation free status for work on the area of genome service industry.

The NIH initiated the Korea Biobank Project in 2008 and established the Korea Biobank Network, composed of the National Biobank of Korea, 17 regional biobanks which are housed in university hospitals and two collaborative biobanks[xvi]. As of January 2020, the network had collected data from 929,405 individuals[xxiii].

Under the guidance of the Ministry of Science and ICT (MSIT), the Center for Integrative Omics and Precision Medicine was established in 2017 to carry out research on integrated multi-genomics-based precision medicine for colon cancer. The project, operating with a budget of GBP 237mn, is expected to run until 2026, with the goal of developing platforms for the diagnosis, prognosis and treatment of intestinal cancers[xxiv].

In addition, the MSIT, together with the MoHW and Ministry of Trade, Industry and Energy (MOTIE), is also funding a national bio big data construction pilot project aiming to carry out Korean population data analysis to develop AI-based prediction solutions for cancer and rare diseases. The project, named the "K-DNA project", was awarded in October 2020 to a consortium comprised of sequencing companies Macrogen, Theragen Bio and DNA Link. Normally competitors in the local market, the three companies teamed up and will receive a budget of GBP 946mn over the course of the K-DNA project to carry out whole genome sequencing (WGS) work, with a targeted completion date of 2029[xxv].

AI-based Healthcare Solutions

According to market research firm Markets and Markets, Korea's AI healthcare market size was estimated to be worth GBP 26.6mn in 2020 and is expected to grow to GBP 260mn by 2026[xxvi]. As of May 2022, over ,110 AI-based medical devices approved by the MFDS in Korea, and these are governed by 9 guidelines[xxvii].

Although Korea got off to a late start compared to other countries, we have seen great progress in genome data collection programs over the past few years. The creation of data bio banks has led to greater synergy between companies and hospitals, and Korea is now in the phase of developing the precision medicine program infrastructure needed for clinical settings. The commercialization of locally developed precision medicine programs is expected to start in 2030, and thus, I believe precision medicine is the future for Korea's medical industry.

HongSeok Lee, Secretary Director – Research Center for Precision Medicine Technology Development

Inspired by IBM's Watson the Korean government set out to develop an AI-based medical service in May 2018. The "Dr. Answer" consortium consists of 25 local hospitals, 21 AI software developers including DEEP Bio, JLK Inspection and Kakao Brains while being led by Seoul's Asan Medical center[xxviii]. The platform analyzes patients' medical data and offers personalized diagnostics as well as treatment plans for major diseases.

The current iteration of the platform solution, called Dr. Answer 2.0, is comprised of 24 software programs, and can help diagnose 12 diseases including cancers, cardiac disorders and Alzheimer's[xxvi]. A major advantage of these programs is that the database uses Korean data increasing reliability for medical providers in a largely homogenous country. These platforms will become eligible for reimbursement upon approval by the MFDS. Clinical trials are underway at 26 hospitals in Korea, as well as Saudi Arabia and countries in Africa[xxvi].

Local players are also looking to do business with overseas companies, creating potential partnership opportunities for UK companies. In July 2021, Lunit and Guardant Health, a leading precision oncology company, announced a partnership agreement including a GBP 21mn investment for Lunit. As part of the agreement, Guardant Health will eventually use Lunit's AI platform to develop new precision oncology products to improve cancer care for patients[xxix].

Opportunities

Korean big data healthcare initiatives have focused on creating precision medicine applications and programs to fight cancer, which is responsible for approximately 27% of total illness-related deaths in Korea[xxx]. Hospitals, in collaboration with foreign digital healthcare companies such as Syapse, Molecular Health, IBM Watson and Microsoft Azure, are currently working to establish their own personalized cancer medicine centers using big data technologies. The government has shown that it is open to working with foreign technologies, as evidenced by its collaboration with Switzerland-based company Clinerion to develop a precision medicine hospital information system and a precision medicine-based cancer diagnosis system.

While Korean companies have made good progress in developing solutions for digital therapeutics, doctors are moving cautiously in the implementation of such solutions. Nonetheless, there is a consensus within the medical community that treatment for cognitive disorders can be digitalized and have positive outcomes.

Shihang Lee, Associate, Digital Health Practice – Bae, Kim & Lee

As nearly all of Korea's population is covered under its national health insurance system, Korea has a large quantity of medical data. However, strict regulations create hurdles to utilizing this data. In spite of this, bio database projects and precision medicine systems are creating growing opportunities for UK companies with big data-based technologies.

The number of approved AI-based medical devices continues to increase rapidly indicating Korea's eagerness to utilize such technologies. An update to the country's reimbursement model for AI solutions is required as there is a gap between the new technologies available and the evaluation criteria used but it is anticipated that changes to the current reimbursement system will occur as the growing AI market develops.

Both the UK and Korean governments, in each respective territory, are supporting initiatives for funding and raising awareness around the clinical benefits of precision medicine programs and resolving issues regarding data usage. As both countries work towards achieving the same goals, this will result in significant opportunities in Korea for UK companies with strengths in precision medicine platforms, data analytics and data interpretation, as well as applying analytics to develop big data-based medical diagnostic and treatment devices, which are all necessary to boost the adoption rates of big data solutions. We recommend that UK companies interested in this market work together with local Korean partners to enter the market as this will be helpful for understanding local market conditions and regulations.

Although the number of approved AI-based medical devices continues to increase in Korea, a reimbursement framework for AI solutions is yet to exist, creating difficulties for companies trying to commercialize their products. Hospitals and developers must prove the cost-effectiveness of implementing AI solutions to receive insurance coverage, however, they face challenges in doing so due to an outdated evaluation system. Thus, some AI companies choose not to apply for reimbursement and, instead, sell their solutions using a subscription-based model.

Shihang Lee, Associate, Digital Health Practice – Bae, Kim & Lee

BLOCKCHAIN IN HEALTHCARE

Korea has one of the largest blockchain markets in the world estimated at nearly GBP 145mn in 2021[xxxi]. There are numerous start-ups and significant government interest in developing this technology domestically. In 2019, the Ministry of Science and ICT announced a budget of GBP 700mn solely devoted to blockchain development, and Korean companies such as SK Telecom, Samsung SDS and LG CNS are moving quickly to develop products and services utilizing blockchain technology[xxxii].

MediBloc, Korea's best-known blockchain-based digital health company, has developed an EHR solution and a solution for integrating healthcare data – all based on blockchain technology. MediBloc has partnered with a total of 20 medical institutions, including Severance Hospital to develop a blockchain-based medical information platform.

Creating secure data storage, integrated health record systems and safe data sharing platforms are other areas of focus for companies specialized in blockchain-based healthcare applications. Myongji Hospital has partnered with local tech company, BICube, to develop a platform based on blockchain technology to create an HIE system. RedWit is working to develop a solution for researchers to encrypt research work through blockchain. Crypto Med Innovation develops AI software for health data collection and protects that data through encryption using blockchain.

Opportunities

Korea is looking to blockchain technologies for applications like improving the security of electronic health records, medical supply chains, payment methodologies, insurance claims, research capabilities, HIT and data ownership. Currently, several healthcare-related blockchain companies such as MediBloc, Prasm and ICONLOOP are collaborating with healthcare providers and businesses to build blockchain-based medical record databases and big data centers for hospitals to securely store, exchange and use patient data. They are also commercializing this data by allowing life sciences companies to develop advanced healthcare products such as disease prediction and treatment services.

Government support through deregulation and investment creates opportunities for UK blockchain companies to partner with local firms on both private and government projects in the healthcare sector. Busan, Korea's second largest city, was designated a special regulation-free zone for blockchain technology in 2019, creating an ecosystem for companies to develop and use blockchain-based solutions without concerns over regulatory barriers. Blockchain development companies are also offered special tax relief packages for R&D expenses which is further helping spur the creation of blockchain based digital health technology[xxxiii]. This rapidly developing area will create an expanded market for companies in the UK that have developed technologies that enable safe storage, secure transfer and control of medical records as well as flexible payment methodologies.

TELEMEDICINE

The use of telemedicine in Korea lags other countries as full-scale implementation is still prohibited by law. Nonetheless, Korea has made significant technological advances in telemedicine and has a relatively long history of implementing pilot programs beginning in the 1990s for people living in remote areas of the country where hospital access is limited, as well as for disabled patients. In 2002, Korea revised regulations to allow telemedicine between doctors and medical personnel, although telemedicine between doctor and patient remains largely banned.

At the time of his election in 2017, former President Moon was against the use of telemedicine, however, increased calls to permit the use of telemedicine from various groups led to a softening of this stance[xxxii]. In 2019, the government designated Gangwon province as a regulation-free zone for digital health technologies and allowed full usage of telemedicine between doctors and patients[xxxiv]. This has not helped to ease strong opposition from medical doctors' groups who argue that telemedicine would lower the quality of care and allow Korea's Big 5 hospitals to further dominate the Korean healthcare market. There are also concerns from developers of telemedicine applications that the payment for doctors who participate in such programs would not be enough to entice them to want to work in such areas.

Despite opposition to telemedicine, some hospitals and organizations including Seoul National University Hospital and the Korea Telemedicine Society have argued in favor of deregulation to open up the domestic telemedicine market. Korea has made some progress in recent years, most notably in 2020, when the National Healthcare Reimbursement Act was amended to allow telemedicine services to be covered under Korea's National Health Insurance. Currently, regulations allow doctor-to-patient tele-monitoring for some diseases including diabetes and peritoneal dialysis.

Additionally, the Infectious Disease Control and Prevention Act (IFDCPA) was amended on December 15, 2020, to include a legal basis for telemedicine in the event of serious alert levels relating to infectious disease. Telemedicine is therefore allowed under the IFDCPA, but no amendment has been made to the Medical Service Act to allow the use of telemedicine which is preventing telemedicine services from being created. Going forward President Seok-Yeol Yoon is promising to expand telemedicine pilot projects to target underserved communities and regions. Large-scale implementation of such services is yet to be confirmed.

Impact of COVID-19 on Telemedicine

During the COVID-19 pandemic, a legal framework for the use of telemedicine was created with the amendments made to the IFDCPA. The MoHW issued an administrative order allowing healthcare providers to implement telemedicine services to limit the amount of face-to-face contact among people at hospitals and clinics to decrease virus transmission. Severance Hospital then introduced a telemedicine application called My Severance for doctors to provide inpatient

care remotely. Also, medication delivery services, normally prohibited in Korea under the Pharmaceutical Affairs Act, were made possible during the pandemic.

During this trial period, a majority of patients and doctors expressed satisfaction with the quality and convenience of telemedicine during and wanted to continue the use of telemedicine after the end of the pandemic. However, the MoHW's administrative order expired in November 2021 as the government relaxed restrictions and implemented a 'living with COVID-19' strategy. As no amendments to the Medical Services Act were made to allow the regular use of telemedicine, regulations that existed prior to the COVID-19 pandemic were reintroduced. Nevertheless, companies and industry experts are lobbying for the continued use of telemedicine in hopes of allowing the domestic market to grow.

Opportunities

Although full-scale implementation of telemedicine is still restricted by the Medical Services Act, start-ups such as Healcerion and M3DICINE have collaborated with major Korean conglomerates and healthcare providers to export telemedicine technology and platforms overseas. Medihere developed a solution to provide telemedicine services to ethnic Koreans residing in the US. Medihere's service takes advantage of the huge gap in medical costs between the US and Korea while also alleviating communication difficulties ethnic Korean's might have with their doctors in the US.

The general public's stance on telemedicine changed during the COVID-19 pandemic as more people became in favor of receiving non-face-to-face treatments. In light of this, the National Assembly has proposed amending the Medical Services Act to expand the use of telemedicine. It is not yet known whether these amendments will pass, making it difficult to predict the future of telemedicine, but nonetheless, I think there is a high likelihood of deregulation in the future.

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Several local hospitals have tested telemedicine in collaboration with IT companies by offering limited-scope trial services that follow existing laws. For example, Myongji Hospital partnered with InTouch Health Inc. to create a remote healthcare ecosystem by linking affiliated medical institutions and nursing homes in 2018, and Seoul National University Hospital and KT have been allowed to provide limited telemedicine services to help select remote areas in Korea. KT also has an entire business unit, KT Enterprise, with a department dedicated to developing digital health solutions.

According to the Hyundai Research Institute, Korea's market would be worth GBP 1.5bn if only 20% of the population were to use telemedicine[xxxv]. Although currently limited to designated pilot programs and a push from interest groups has been growing after positive feedback was reported during the use of telemedicine during the COVID-19 pandemic. Despite this, it seems unlikely that deregulation of telemedicine will happen in the near future, therefore, it is recommended that UK companies consider partnering with local firms or consider Korea a long-term market and creating plans to implement when deregulation comes closer to fruition.

CONSUMER HEALTH ELECTRONICS

Korea has the highest penetration of smartphones in the world with 93% of adults owning a smartphone, leading to a rapid integration and burgeoning market for smart wearable devices[xxxvi]. Samsung Electronics is investing heavily in wearable devices and healthcare applications with its Galaxy Watch, Galaxy Fit and Galaxy Buds products, as well as Samsung Health and Samsung Health Monitor apps. In April 2020, SK Telecom announced a partnership with Ariacare Korea and Happy Connect to provide nursing home care to elderly people using its AI technology and AI speaker product, NUGU[xxxvii].

Products in the Korean consumer health electronics market include InHandPlus, a smartwatch that provides medication management functions to the watch wearer. Another start-up company called Welot developed a smart belt that can track a person's fitness level and waist size by using magnetic sensors located in the belt. A medical device company called EOFlow developed a small, wearable insulin pump called EOPatch that received regulatory clearance from the MFDS in 2018. The company began clinical studies of its product on people with type 2 diabetes in Korea in October 2021.

Under the Korean New Deal, which forms part of the government's blueprint for the Fourth Industrial Revolution, there are plans to promote the concept of an 'untact' society (contact-free, a term coined during the COVID-19 pandemic) during the post-COVID-19 era. A major part of this includes

developing smart medical and care infrastructures. As a first step and to encourage local development of products, the government is planning to purchase and distribute consumer health electronic products providing digital health capabilities to people with chronic ailments and the elderly, such as wearable devices for monitoring high blood pressure and IoT sensors for measuring heart rate and blood-sugar levels.

Opportunities

Korea is estimated to be the third largest market in the Asia Pacific region for wearable devices[xxxviii]. In addition to the growing healthcare industry and consumer awareness towards health and fitness, increasing government support through deregulation and several policy initiatives are driving this sector. Samsung Electronics and LG Electronics' investment into healthcare applications and wearable devices has led to new and growing market opportunities in the consumer health electronics sphere.

Most notably, Samsung Electronics' investment into healthcare applications and wearable devices has led to new and growing market opportunities for consumer health electronics. The Korean government is also supporting this industry, and in an effort to boost consumer health management applications and wearables, the government announced in 2018 that personal healthcare management systems such as blood pressure, pulse and stress sensors were to be a focus for new policy initiatives around smart healthcare technology.

The Korean government has expressed concern over the health of the country's increasing elderly population, particularly over its strategy on how to serve a large greying population suffering from disorders such as Alzheimer's and dementia. Medical experts are looking towards wearable and IoT solutions as a possible method for monitoring patients suffering from such disorders, and the government has expressed a viewpoint that implementation of such wearables could be a way to address its worries on the health of the elderly.

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In February 2019, Huinno's Memowatch, a wearable electrocardiogram (ECG) measuring device that sends data to doctors for patient monitoring, became Korea's first product exempt from regulations under the government's regulatory sandbox program[xxxix]. The Memowatch was eventually approved for reimbursement in 2020, establishing a framework for companies developing wearable healthcare products to become eligible for reimbursement[xxxvii]. In May 2020, Samsung Electronics also received approval from the Ministry of Food and Drug Safety for the ECG measurement and blood pressure measurement functions on its Samsung Health Monitor app. These examples open further opportunities for UK digital health companies developing similar products to enter the Korean market.

Korean conglomerates are actively seeking collaboration with foreign companies in the digital health sector, with an eye towards integrating new and innovative technologies into their products. For example, Samsung Electronics recently partnered with Myotest, a Swiss company providing analysis of biometric data, to provide running analysis on its Galaxy Watch product[xl]. There will be continuous opportunities arising for new technologies which can do things like monitoring vital signs and devices such as automated digital insulin delivery systems with dosage regulation and tracking. The Korean consumer health electronics market also offers strategic opportunities for UK companies that have strong technologies enabling health related connectivity devices, and the secure transfer and maintenance of patient data on wearable devices.

A focus for companies during the COVID-19 pandemic was the development of wellness monitoring solutions in collaboration with local and provincial governments, particularly for quarantine purposes. Potentially, the largest buyers of these wellness solutions could be regional governments.

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OVERVIEW OF OPPORTUNITIES

As outlined in Korea's framework for future development, the government sees the digital health industry as an important new growth engine during the post-COVID-19 era. The current administration is prioritizing businesses that are active in the field of digital health technologies to develop the country's smart medical infrastructure in the coming years.

As is the case in the UK, Korea faces issues regarding increasing healthcare costs and an aging population. UK companies with proven technologies for addressing these issues will likely find a receptive audience in Korea for their products, especially if they team up with a local partner. Companies may also find opportunities to use Korea as a testbed before launching products back home especially considering as the government has several regulation free zones aimed at creating new technologies in this area.

In the face of fierce and growing competition, large and established Korean companies are eager to cooperate not only with domestic start-ups but also with foreign digital healthcare companies. As a result, large companies are anxious to acquire or form partnerships with start-ups and scale-ups with promising technology to reduce the technological gap with countries that have more advanced digital healthcare expertise. This development represents a strong opportunity for UK digital healthcare companies seeking investment or partnership opportunities in Korea.

Table 5: Opportunity Areas for UK Companies

Sectors	Remarks
Health IT	Korean medical institutions are highly digitized with high usage rates of EMR/EHR, however, usage rates of HIE solutions remain low. Areas of need include clinical trial management systems, medical imaging platforms, patient monitoring systems, etc.
Big Data	Strong government support and investments for precision medicine and genomics. Increase in the number of approved AI-based medical solutions contributing to a growing market.
Blockchain	Growing collaboration between blockchain companies and medical institutions for developing blockchain-based medical record database, disease prediction services, etc. Government support through deregulation, tax relief, as well as investments make the market attractive.
Telemedicine	Currently blocked by regulation but calls from interest groups supporting deregulation to open domestic market. Positive feedback from doctors and patients on the use of telemedicine during COVID-19 pandemic. Preparation for entering the Korean market is recommended.
Consumer Health Electronics	High smartphone penetration rate and usage of wearable devices among general population. Government also supporting the use of wearable products with digital health functions for monitoring of chronic diseases.

05

KEY REGULATIONS

KEY POINTS

- Regulations around health/medical data privacy, data sharing, and telemedicine for digital health companies in Korea
- Recent regulatory amendments provide clearer guidance on the use of medical data
- AI-based medical devices now receive tailored government regulatory support from the MFDS
  – The review of applications for certification of new products generally takes less than 65 days

One issue hampering the development of HIT, precision medicine and big data-based healthcare technologies in Korea is an unclear set of laws and acts which regulate personal and medical information. The government is aware of this issue and has been trying since 2019 to deregulate and clarify regulations in order to boost the sector.

Potential regulatory changes are expected to occur after the 2022 presidential elections. It is expected that amendments to regulations will allow the general population to have greater access and authority over their own medical data. Patients may then be able to, for example, sell their own medical data to private institutions of their choosing. This new paradigm change is being carefully reviewed by researchers, although the framework for this remains to be seen.

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DIGITAL HEALTH REGULATIONS

Table 6: List of Korean regulatory agencies pertaining to digital health

Name of Agency	Year Established	Remarks
Ministry of Health and Welfare (MoHW)	2010	Regulates social welfare and healthcare systems while working closely with regulatory agencies and institutions
Ministry of Food and Drug Safety (MFDS)	1997	Oversees the registration and approval of medical devices and solutions
Personal Information Protection Commission (PIPC)	2020	Oversees the protection and supervision of personal information
National Health Insurance Service (NHIS)	2010	Oversees Korea's national health insurance and pension systems
Health Insurance Review and Assessment (HIRA)	2000	Assesses costs and reimbursement prices of medical products and services

Source: Intralink Research

Regulations on Data

Korea's Personal Information Protection Act (PIPA) is considered to be one of the strictest data protection frameworks in the world. PIPA stipulates that personal information includes name, national identification number, letter, voice, visual image, and all other information that can be easily combined together to identify a specific individual. According to the Act, any information that, if revealed, may considerably infringe on the data subject's privacy, such as information related to an individual's health or medical treatment, genetic profile, sexual orientation, criminal records, ideology and faith is considered sensitive data. At a practical level, when using most apps or websites in Korea, approval for use of such information is explicitly requested and a reminder of how the data is used is sent by each company to the individual on a yearly basis.

Medical data is regulated by PIPA as it falls under the category of personal information. As such, regulations on personal information are an essential component in digital health as vast amounts of medical data are used. PIPA requires doctors to specify the intent of use and obtain explicit prior consent from patients in order to use or transfer medical data to third parties.

In January 2020, amendments were made to PIPA, as part of the passing of the 'Data 3 Act', to allow pseudonymized data to be processed for statistics, scientific research, and archiving purposes without the consent of the individual[xli]. However, the processing and use of pseudonymized data must adhere to guidelines created by the Personal Information Protection Commission (PIPC) and MoHW. Anonymized data is not subject to PIPA but is regulated by the Bioethics and Safety Act. Nonetheless, it is understood that the same set of guidelines for processing and using pseudonymized data also applies to anonymized data.

Difficulties exist for healthcare organizations and companies to use data for research and commercial purposes as different regulations and guidelines may overlap with each other and create ambiguity. It is essential for digital health companies to understand Korea's data laws in order to stay within the legally allowed scope for use of medical data.

Table 7: List of regulations and guidelines pertaining to medical data

Name of Act	Year Established	Remarks
Personal Information Protection Act	2011	Oversees matters related to personal information including name, national identification number, letter, voice, visual image, and all other information including any information that can be easily combined with other information to identify a specific individual
Bioethics and Safety Act	2003	Protection over processing personal and genetic information of patients
Medical Services Act	2016	Regulates matters related to quality of medical services, requirements for hospitals and medical records as well as prohibition against disclosure of confidential patient information such as treatment options, drugs prescribed
Framework Act on Data Industry Promotion	2021	Framework for development and promotion of domestic industry
Guidelines for De-Identification of Personal Information	2016	Guideline for de-identifying personal information before utilization
Guidelines on Processing Pseudonymized Data	2020	Guidelines for processing and ensuring stability pseudonymized data
Guidelines for Use of Health-Medical Information	2020	Guidelines for the use of pseudonymized medical information

Source: Intralink Research

Medical Services Act

The Medical Services Act regulates matters concerning the quality of medical services, and restrictions on the disclosure of confidential patient information such as treatment options and drugs prescribed. Medical institutions and medical records are also subject to the Medical Services Act, which may overlap with PIPA.

In 2002, the Act was amended to allow telemedicine to be used between physicians and health care providers, however, doctor-patient telemedicine was still not allowed. Due to COVID-19, an administrative order was introduced in February 2020 to allow doctor-patient telemedicine to reduce the transmission of the virus through person-to-person contact at hospitals and clinics, but this order expired in November 2021 when the government implemented its 'living with COVID-19' strategy. Proposals have been made in the National Assembly to amend the Medical Services Act and expand the usage of telemedicine but to date these have not passed. However, pilot programs looking at telemedicine will continue, and telemedicine could be approved in the future.

Framework Act on Data Industry Promotion

A newly created data-related act was passed through a National Council meeting in October 2021, creating the framework, for the first time, for the development and promotion of Korea's data industry. The Framework Act on Promotion of Data Industry and Data Utilization established a new national data policy committee to oversee the regulation of the data industry as well as foster innovation and advancement of data-related companies. It requires local and regional governments to create plans to promote data production, sharing and utilization which must be updated every three years. High interest in the use of data for healthcare from the government can already be seen through the fact that the number of research grants in the area has increased from 3,451 in 2018 to 6,209 in 2022 amounting to hundreds of millions in funding[xlii]. While the law and research grant funding are promising developments, since the enforcement of the act took effect only in April 2022, it remains to be seen exactly what impact this law will have on the use of medical data in the digital health industry in the future.

In Korea, the paradigm of medicine is shifting away from being solely evidence-based and becoming more data-oriented. The new Framework Act on Data Industry Promotion is set to outline the utilization of data across various industries, including the medical sector. In accordance, the government has designated agencies that will be able to collect pseudonymized data for medical use, including the NHIS, HIRA and KHIDI, to provide support in the creation of more data-oriented hospitals.

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GUIDELINES ON REVIEW AND APPROVAL OF AI/BIG DATA-BASED MEDICAL DEVICES

The Ministry of Food and Drug Safety (MFDS) established formal guidelines for the review and approval of AI and big data-based medical devices in November 2017. The MFDS defines AI and big data medical devices as devices that can assist medical professionals in the diagnosis, management and prediction of diseases based on the analysis of medical big data and AI technology. Certain types of medical software can therefore be categorized as medical devices. For example, software that analyses a CT scan of a lung to diagnose the existence or stage of cancer falls under the category of medical device.

However, not all medical software is considered a medical device. For example, software that analyses health data and provides dietary, exercise or lifestyle advice is not considered a medical device. Also, software that supports administrative work of a medical institution or software that manages medical records not related to the treatment or diagnosis of disease fall outside of the medical device category.

The certification process includes a review of product functions and features to verify performance and clinical efficacy. Items that are reviewed include sensitivity, specificity, positive predictive value, negative predictive value, receiver operating characteristic (ROC) curve, as well as area under the curve (AUC). This review process typically does not take more than 65 days.

Medical Device Classes

All medical devices, including software, intended to be used on humans for the diagnosis, treatment or prevention of disease need to have a category classification and receive pre-market approval by the MFDS in Korea. There are four categories for medical devices depending on their potential risk to human health. Class I (lowest risk level) products do not need to be registered and can simply be reported and sold in Korea. Class II, Class III and Class IV (highest risk level) products need to go through relevant registration procedures before they are approved for the market. Regardless of classification, all digital health related medical devices (e.g., AI-based diagnostics and treatment solutions) must be approved by the MFDS.

REIMBURSEMENT

Medical device manufacturers and market authorization holders can apply to have their products considered for reimbursement by end users after the registration of a medical device with MFDS is completed. The Ministry of Health and Welfare (MoHW) in collaboration with Health Insurance Review and Assessment Service (HIRA) published the "Guideline for Evaluating the Eligibility of Innovative Medical Technologies for Medical Care Benefits" in December 2019. However, these guidelines only applied to AI-based technologies related to medical imaging or 3D printing-based medical technologies. After receiving requests from medical professionals and related associations, the MoHW and HIRA published an updated version of the guidelines, this time including AI-based software technologies for pathology in December 2020.

The process to apply for reimbursement eligibility starts with the National Health Technology Assessment (NHTA). This phase decides the initial eligibility of a technology for reimbursement. According to the guidelines, an innovative medical technology is a technology that provides interpretation and diagnoses by using AI-based medical devices (software, etc.) that analyses digital-based data converted from pathological information of a specimen collected from the human body.

Following initial approval, additional regulatory agencies such as Health Insurance Review and Assessment Service (HIRA) will review the "Intended Use", "Mechanism of Action" and "Performance" of the technology/solution. Technologies that improve a doctor's efficiency or provide assistance with reading simple numerical measurements and/or location detection (e.g., tumor detection) are classified as eligible for fixed reimbursement amounts. If the technology is proven to be more beneficial to the patient and more cost effective compared to existing practices, then the additional value will be recognized by increasing the amount of reimbursement (compensation for item development, reclassification etc.). It is unknown how many AI-based software solutions have been granted reimbursement so far.

Companies should also be aware of potential issues they may have when applying to Korea's reimbursement system. HIRA reviews and sets reimbursement coverage and pricing for medical devices, and as part of the review process, an evaluation of a product's cost-effectiveness is required. However, HIRA has not yet published proper evaluation criteria for products using new technologies, such as AI medical solutions. This could lead to lower than desired reimbursement coverage and pricing of a product. Thus, medical institutions may face difficulties in implementing new technologies due to the risk of receiving lower insurance compensation, potentially creating hurdles for companies wanting to commercialize their products in Korea.

06

MARKET ENTRY STRATEGIES

KEY POINTS

- Partnering with local distributors or resellers is advised for foreign companies
- A Korea based sales and customer support team is necessary due to language and cultural barriers including Korean consumers high expectations regarding after sales service
- Foreign companies can apply to participate in government-led projects but there are barriers:
  – Culture, language, business environment, etc.
  – Preference towards domestic companies for such projects

Korea offers strong opportunities for UK digital health companies with the government, major hospitals, large conglomerates and a growing number of tech start-ups all investing heavily in the field. Like most developed countries, Korea is grappling with rapidly increasing medical costs due to its fast-ageing population and an increased rate of chronic disease. These factors, along with highly developed ICT infrastructure and willingness to embrace new technologies, make Korea an attractive market for UK digital healthcare businesses. UK businesses can enter the Korea market directly, by appointing a partner or by setting up an office in Korea.

Direct Sales from the UK

The simplest market entry option is for UK companies to sell or license a particular digital health technology directly to a Korean partner who would distribute the technology in Korea. The main downside of a direct sales approach is the lack of local language and time zone support, as Korean customers tend to be particularly demanding of companies in terms of product after service support. This can be mitigated by using a local agent or business development consultancy, such as Intralink, capable of bridging time zone, language and cultural gaps without the long-term commitment of local incorporation and hiring. Market-specific factors to consider include:

- Do we have a strong differentiator – something that sets us apart from our competitors in the global market?
- Do we have a strong track record in other major markets? Korean companies are not usually the first to distribute new technologies without an extremely strong track record
- Are we willing and able to localize the product to local regulations and market conditions?
- Are we ready to provide a Proof of Concept (PoC) test at little or no cost to the customer? Korean companies will look to minimize upfront costs and will want strong data driven results before committing
- How do we provide after-sales support? Korean customers expect high-quality, local-language support
- Do we understand the local regulations, particularly in relation to data? Do we need to adjust our business model to adapt?

Appointing a Reseller or Distributor

A more common way to approach the market is to seek a partnership with an established local company which complements your product, has experience in the target sector and can help navigate the legal environment. A local channel partner can provide services such as certification, registration, pre-sales, sales, consulting, installation, technical training, service maintenance and technical support in the Korean market. Even large multinationals take this route in the early stages of market entry. Market specific factors to consider when seeking a partner include:

- Does the partner already serve the type of customer our product is targeting?
- Does the partner have a good understanding of the market in general and my particular application?
- Does the partner already offer solutions similar or complementary to our offering?

- Is the partner focused on short-term wins or will they be able to drive our business in the long run?
- Does the partner have specific experience with public sector projects?
- Are we comfortable communicating with the local partner and are they transparent with us?

Establishing a Local Presence

There are three main ways of establishing a local presence: (1) a liaison office, (2) a branch office or (3) a local corporation through foreign direct investment (FDI). Setting up a liaison office is a simple process; but a liaison office can only perform non-profit generating activities in Korea such as market surveys, research and development and quality assurance. Opening a branch office can be a complicated process that requires documentation to be translated, but it allows for sales activities and the exchange of revenues with the head office. The most common process for an overseas company to open a branch office in Korea is through FDI, where an initial investment exceeding approximately GBP 70,000 is made by the head office, which in return owns stock in the branch. The local corporation leads independent activities and is authorized to perform direct transactions. Market-specific factors to consider when establishing a local presence in Korea include:

- Is our business generating enough revenue in Korea to consider a local presence? Businesses usually consider establishing a local presence after several years of sales (either direct or through a partner)
- Is Korea a strategic market for us, either in terms of securing use-cases or securing further funding?
- Do we need to engage in profit generating activities?
- Will we transfer staff from our head office or hire local staff? In Korea, visas can be difficult to secure for foreign employees and social insurance contributions and severance pay must be paid to all staff that complete one year of employment. An employer's share of these costs equates to 18% of salary
- What location shall we pick for our local presence? Scouting, negotiating, and conclusion of contracts are time-intensive processes that often are hard to conclude without local support.

Big 5 Hospitals

Asan Medical Center (AMC)

Founded in June 1989, Asan Medical Center is the largest medical institution in Korea with a total of 2,715 beds occupying about 85,000 square meters. Asan Medical Center is the parent hospital of eight hospitals under the ASAN Foundation which was established in 1977. Asan Medical Center sees 11,680 outpatients and 2,427 inpatients, while performing about 66,838 highly sophisticated surgeries per year. Known as a "chaebol hospital" due to its affiliation to Hyundai Group, Asan Medical Center has 8,796 employees, including 1,749 doctors and 4,167 nurses and is the most visited hospital in Korea today.

Asan Medical Center expanded its Digital Information Innovation Center as it pushes towards its goal of becoming a fully digitalized hospital. The hospital currently utilizes AI to automate bed assignments and nursing department schedules and internally built a voice recognition real-time medical image reading service. It also integrated platforms for data management and development of precision medicine programs.

Severance Hospital

Established in 1885 in Seoul, Yonsei University's Severance Hospital is the second largest hospital with 2,437 hospital beds, 1,192 physicians and over 4,000 additional staff. Severance Hospital each year performs more than 44,000 surgeries and sees 6,850 outpatients and 2,300 inpatients on average per day. With its five-adjoining specialty centers, Severance Hospital offers services to its patients through more than 60 clinical departments and divisions, including three specialty facilities (Cancer Hospital, Spine Hospital and Dental Hospital).

As part of its digital transformation strategy, Severance Hospital is working to build a smart hospital platform for big data and precision medicine for its current Seoul facility as well as new Songdo Severance Hospital scheduled to open in 2026. To achieve its goal, the hospital established a new big data division and plans to establish a digital transformation division, as well.

Samsung Medical Center (SMC)

Founded in 1994, Samsung Medical Center is the third largest medical institution in Korea with a total of 1,989 beds, 1,309 doctors, 2,421 nurses and 171 researchers at the center. Samsung Medical Center sees 5,823 outpatients, 253 inpatients, and 210 emergency patients on average per day while performing about 50,000 surgeries per year.

Samsung Medical Center established a digitization strategy to achieve its goal of becoming the 'hospital of the future'. The hospital recently announced plans to develop a big data service platform utilizing medical data called the Learning Health System (LHS) and is also a participant in a government initiative to develop a cloud-based precision medicine hospital information system called the Precision-Hospital Information System (P-HIS). It also plans to create an ecosystem for digital health innovation by introducing solutions including VR treatment devices, an AI-based patient self-management platform, and digital therapeutics.

Seoul National University Hospital (SNUH)

Established in June 1885, Seoul National University Hospital is one of the oldest and biggest hospitals in Korea with 1,761 beds. SNUH is the only national hospital among the Big 5 and sees 6,132 outpatients and 1,497 inpatients on average per day while performing about 40,000 surgeries per year. SNUH employs 1,947 doctors, 2,916 nurses and 936 medical technologists.
SNUH recently announced the establishment of both a planning and working committee for innovative medical technology R&D as it works to achieve its goal of digital transformation. The hospital has already introduced a solution platform for non-face-to-face treatment and operates a cloud-based big data research platform called SUPERB (SNUH Utility for Practice, Education and Research using Big data).

Seoul St. Mary's Hospital

Founded as Kangnam St. Mary's Hospital in 1980, Seoul St. Mary's Hospital has a comprehensive healthcare system composed of 41 clinical departments and 22 special clinical centers. The hospital has a total of 1,374 beds and around 4,300 medical and technical staff at the center. Seoul St. Mary's Hospital sees about 4,663 outpatients and 1,205 inpatients on average per day and performs about 40,000 surgeries per year.
Seoul St. Mary's Hospital established a 10-year plan for digital transformation where its Digital Healthcare Department oversees multiple teams working to implement the hospital's roadmap. In its roadmap, the hospital plans to utilize new technologies including AI, big data, IoT, and healthcare robots. The hospital also participated in a smart hospital initiative during the COVID-19 pandemic called BIC Plus (Best Infection Control Platform for use) where it introduced digital health solutions including an AI-based medical record system and a program for providing contactless nursing care.

Source: Korea Biomedical Review[vi]

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