



INVESTMENT  
OPPORTUNITIES  
IN KOREA

# Healthcare & Bio



KOTRA 20-003

## Investment Opportunities in Korea \_ Healthcare & Bio

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\* Figures on the report show the likely adjustment of average yearly currency rates from Korean Won (KRW) to the US dollar (USD). A rate adjustment is adopted particularly reflecting the recent average market variations to eliminate the valuation effects arising from movements in exchange rates in case when the data expressed shows an annual growth rate on the paper.

\* Rate adjusted figures are rounded off, but the sum is correct down or up to the decimal when the rounded values are not equal to the adjustment.

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# 01 Industry Trends

## Definition and Classification

- The biopharmaceutical industry develops medicines to prevent and treat human or animal diseases.
- Medicines are classified into synthetic drugs and biopharmaceuticals according to their ingredients.
  - Synthetic drugs are low-molecular weight drugs produced through chemical synthesis reactions, and most of them consist of chemicals that can be widely used in many patient groups.
  - Biopharmaceuticals are medicine manufactured using living organisms or materials derived from living organisms (blood, cells, microorganisms, etc.). They are more complex and have higher molecular weight than synthetic drugs.

Classification of Medicine

Classification	Synthetic drug	Biopharmaceutical
First approved drug	New drug	(Bio) New drug
Improvement of efficacy of first approved drug	Improved drug	Biobetter
First replication of approved drug	Generic drugs	Biosimilar

## 1.1

### Market Trends in Korea

#### Korean pharmaceutical production and company status

- The average annual growth rate of the pharmaceutical sector over the past five years (2014-2018) was 6.5%, which is 2.1% point higher than the overall manufacturing growth rate (4.4%).

\* Annual average growth rate (2014-2018): total industry (4.6%), manufacturing industry (4.4%), pharmaceuticals (6.5%)

- Drug production in Korea was USD 19.18 billion in 2018, up 3.7% from USD 18.5 billion in 2017.
  - In 2018, pharmaceutical production accounted for 1.18% of GDP, and the share in the manufacturing sector was 4.35%, the highest level in the last five years.
- The number of drug companies in 2018 was 399 for finished drugs and raw

materials, and 132 for herbal medicine. As for the number of items, there were 19,520 for finished medicines, 1,590 for drug substances and 5,110 for herbal medicines.

### Overall Production of Pharmaceuticals by Year

(Unit: number of companies, number of items, %, USD 100 million)

Classification	Number of companies	Rate of change	Number of items	Rate of change	Production amount	Year-on-year growth
2014	625	1.5	29,218	8.4	149	0.3
2015	551	-11.8	25,890	-11.4	154	3.4
2016	542	-1.6	26,397	2.0	171	10.8
2017	577	6.5	26,293	-0.5	185	8.3
2018	531	-8.0	26,220	-0.3	192	3.7

Source: Ministry of Food and Drug Safety, Drug production, July 2019.

Note: Starting in November 2014, the in vitro diagnostic manufacturing industry was separated into medical devices and therefore excluded from the production.

### Main characteristics of the Korean pharmaceutical market in 2018

- (Production) Production increased mainly on prescription drugs among finished drugs.
  - Finished drug production recorded USD 16.9 billion, a 5.7% increase from USD 16 billion a year earlier, while drug substance was USD 2.3 billion, down by 8.7% from USD 2.6 billion in the previous year.

### Production of Drug Substances and Finished Drugs by Year

(Unit: USD 100 million, %)

Classification	Drug substances	Rate of change	Finished drugs	Rate of change	Total production	Rate of change
2014	19	-4.7	130	1.0	149	0.3
2015	19	-1.2	135	4.0	154	3.4
2016	22	17.0	148	9.9	170	10.8
2017	26	13.5	160	7.5	186	8.3
2018	23	-8.7	169	5.7	192	3.7

Source: Ministry of Food and Drug Safety, Drug production, July 2019.

Note: Drug substances include herbal medicine raw materials.

- Among the finished drugs, prescription drugs amounted to USD 14.2 billion (84.0%), and non-prescription drugs amounted to USD 2.7 billion (16.0%), and the production of prescription drugs increased by 6.8% compared to the previous year's USD 13.3 billion.

### Production of Prescription and Nonprescription Drug by Year

(Unit: USD 100 million, %)

Classification	Nonprescription drug (over-the-counter drug)			Prescription drug (Specialty drug)		
	Number of items	Production amount	ratio	Number of items	Production amount	ratio
2014	6,075	22	16.9	12,282	108	83.1
2015	5,624	22	16.4	12,283	113	83.6
2016	5,477	24	16.4	13,069	124	83.6
2017	5,652	27	16.8	13,639	133	83.2
2018	5,336	27	16.0	14,203	142	84.0

Source: Ministry of Food and Drug Safety, Drug production, July 2019.

- (Export) Pharmaceutical exports in 2018 were USD 4.673 billion, an increase of 14.8% over 2017, the largest amount of exports ever.
  - Biopharmaceuticals accounted for a greater portion of total drug exports (33.4%) than total drug production (12.4%), of which biosimilars(generic biopharmaceuticals) accounted for 22.9% of total exports.
    - \* Comparison of production results: (All drugs) USD 11.7 billion (Biopharmaceuticals) USD 2.3 billion
  - By country, U.S. export ranked first at USD 502.44 million, followed by Germany (USD 460.7 million), Japan (USD 456.86 million), China (USD 403.17 million), and Turkey (USD 385.34 million).
  - Exports to the U.S. (USD 502.44 million) increased by 30.2% compared with the previous year (US USD 386 million). Exports to Germany (108.3%) in Europe, and Turkey (136.9%), Taiwan (31.6%), and Indonesia (47.7%) in Asia recorded the largest increase.
- (Import) Drug imports in 2018 amounted to USD 6.5 billion, an increase of 16.5% compared to USD 5.5 billion in 2017.
  - By country, the U.S. ranked first (USD 830.38 million), followed by the United Kingdom (USD 743.63 million), Germany (USD 737.92 million), China (USD 732.73 million), and Japan (USD 570.03 million).

## Exports and Imports of Pharmaceuticals by Year

(Unit: USD million, %)

Classification	Export	Rate of change	Import	Rate of change	Balance of trade
2014	2,415	13.5	5,217	8.2	-2,802
2015	2,947	22.0	4,950	-5.1	-2,003
2016	3,120	5.9	5,636	13.8	-2,516
2017	4,071	30.5	5,579	-1.0	-1,508
2018	4,673	14.8	6,501	16.5	-1,828

Source: Ministry of Food and Drug Safety, Drug production, July 2019.

## 1.2

### Industrial Competitiveness

## Korea leading the world in clinical trial competitiveness

- According to the Korea National Enterprise for Clinical Trials, Korea ranks 7th in the world for global clinical trial market share.

\* Ranking of Korea by year: 7th (2014) → 7th (2015) → 8th (2016) → 6th (2017) → 7th (2018)

\* Country rankings (2018): (1st) the U.S., (2nd) UK, (3rd) China, (4th) Germany, (5th) Canada

- Seoul remains the world's top in terms of city share

\* Rankings of Seoul by year: (1st) (2014) → 2nd (2015) → 3rd (2016) → 1st (2017) → 1st (2018)

\* City rankings: (2018): (1st) Seoul, (2nd) Houston, (3rd) Madrid, (4th) New York, (5th) Miami

## Korea listed on the EU whitelist

- In May 2019, Korea became the 7th country to be listed on the EU white list (countries exempt from written GMP written confirmation)
  - Korea, listed 7th, after Switzerland, Australia, Japan, the U.S., Israel and Brazil
  - In recognition of the GMP operating system for Korean drug substances or the quality of drug substances of Korean pharmaceutical companies, Korea is now exempt from the written GMP confirmation requirement when exporting Korean drug substances.

\* Good Manufacturing Practice (GMP): Pharmaceutical manufacturing and quality control standards established by the World Health Organization (WHO)

\* Written GMP Confirmation: A document by which the regulatory authority of the producing country confirms that the drug substances produced by the pharmaceutical company have been managed according to the same standards as EU GMP

## Medication GMP mutual recognition scheduled with Switzerland, a leading pharmaceutical country

- On June 6, 2018, Korea and Switzerland agreed to enter into a Pharmaceutical GMP Agreement on Mutual Reliance (AMR).
  - Domestic procedures for execution of the bilateral agreement are in progress, and expected to be finalized by the end of 2019.
  - \* Agreement on Mutual Reliance: An agreement to mutually acknowledge the results of drug GMP due diligence results
- Korea's first mutual recognition with another government in the field of pharmaceutical GMP
  - Mutual GMP due diligence is exempted by submitting a certificate of GMP compliance when a company in either country applies for a drug license for export to the other country.

## Promoting international harmonization of the pharmaceutical sector, including joining the PIC/S and the ICH

- In 2014, Korea became a member of the 'Pharmaceutical Inspection Co-operation Scheme (PIC/S)' and strengthened the GMP (Good Manufacturing Practice: Pharmaceutical Manufacturing and Quality Control Standards) to the same level as the U.S., EU, and Japan to improve product quality in Korea.

\* Pharmaceutical Inspection Co-operation Scheme (PIC/S): The only international consultative institution that establishes and leads international standards of pharmaceutical GMP

- In 2016, Korea officially joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as a full member, internationally recognized as an advanced country in all areas of pharmaceutical regulation, including drug approval, screening and follow-up management.

\* International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: An international council led by advanced pharmaceutical countries such as the U.S. and Europe, which leads the regulation on the safety, efficacy, and quality of medicine

### Leading biosimilar development and international regulations

- In Korea's biopharmaceutical industry, the development of biopharmaceuticals has led to the expansion of research bases and the creation of global success cases, and, in particular, Korea is expanding the development of biosimilars to secure leadership in the global biosimilar market.
- The world's first antibody biosimilar "Remsima" of Celltrion, INC. Korea obtained approval from the European Medicines Agency (EMA) in July 2013 and from the U.S. FDA in April 2016.
- Korea was elected as Chairman of the Biosimilar Regulatory Harmonization Working Group at the IPRF Forum in 2013 and continues to serve as Chairman for the second term from 2017 to 2019.

\* IPRF: International Pharmaceutical Regulators Forum

### Exempt from on-site due diligence when delivering Korean vaccines to international organizations

- In December 2016, Korea entered into an agreement with the WHO for the vaccine sector, which stipulates that when Korea's vaccines are delivered to international organizations, they will be exempted from on-site WHO GMP due diligence (drug manufacturing and quality assurance).
- This shows that the WHO has officially recognized that the Korean vaccine safety management system is internationally reliable.

### Bio/medical sector: 1st place in VC investment

- As of 2018, VC investments in the bio/medical sector totaled at USD 760 million, which accounts for the largest part of the total VC investment of USD 3.1 billion.

#### VC Investments by Industry

(Unit: USD 100 million)

List of industries	2016	2017	2018
ICT manufacturing	0.9	1.4	1.4
ICT Service	3.7	4.7	6.8
Electric / Machinery / Equipment	1.9	2.2	2.7
Chemistry / Material	1.4	1.2	1.2
Bio / Medical	4.3	3.5	7.6
Video / Performance / Record	2.4	2.6	3
Game	1.3	1.2	1.3
Distribution / Service	2.3	2.5	5.2
Others	1.4	1.2	1.9
Total	19.6	20.4	31.1

Source: Korea Venture Capital Association, Jan. 2019

## 1.3 Promising Fields in Korea

### Policy development and support areas of the Korean government

- The Korean government grants funds and tax and location support for high-tech companies in pursuant to the Industrial Development Act
  - Supports are provided to technology and products with high tech intensity and fast tech innovation.
  - The biopharmaceutical sector includes low molecular weight drugs, biopharmaceuticals, regenerative medicines, and medicine-based technologies.

### Advanced Technologies and Products in the Biopharmaceutical Sector

Main Category	Sub-category	Advanced technology and products
Low molecular weight drugs	New concept therapeutics (first in class and unmet medical demand)	Target discovery and verification technology
Biopharmaceutical	Protein therapeutics	Protein- (protein / functional component) fusion technology
	Antibody therapeutics	Multi-specific Antibody production technology
		ADCC / CDC Enhancement technology
	Vaccine therapeutics	Premium therapeutic vaccine development technology
	Gene therapeutics	Therapeutic gene discovery and optimization technology
		Nucleic Acid therapy technology
		RNAi-based gene therapy
Regenerative medicines	Platform for the practical use of functional strengthening cell medication and bio production	High efficiency targeting carrier editing and manufacturing technology
		Human intestinal microorganism identification / production and treatment technology
		Advanced in vivo / external cell differentiation control and analysis technology
		Cell quality standardization and biomimetic disease modeling technology
	Bio-artificial tissue / organ therapeutic agent	Stem cell mass production technology
		Immune cell therapy development technology
		Biocompatible materials and 3D bio-printing material production technology
Medicine-based technology	Drug efficacy and safety evaluation technology	Utilization of 3D biological tissue (organoid) and bio-artificial organ manufacturing technology
	Drug Delivery System (DDS) technology	Biomarker utilization toxicology evaluation technology
	Big data-artificial intelligence based new drug commercialization technology	Insoluble soluble drug property improvement and control technology
		Big Data-AI based new drug platform and evaluation technology

Source: Ministry of Trade, Industry and Energy Public Announcement under Article 5 of the Industrial Development Act (Scope of Advanced Technologies and Products).

• Based on the Restriction of Special Taxation Act, tax credits are granted for research and human resource development expenses for new growth engines and original technology, including the following technology areas in the biopharmaceutical sector.

- Discovery technology of bio new drug candidate material: protein therapeutics, gene therapeutics, antibody therapeutics, stem cell therapeutics
- Defense antigen screening and manufacturing technology: therapeutic vaccine and prevention vaccine
- Biosimilar manufacturing and improvement technology
- Technology to discover candidate substances for innovative new drugs (compound drugs)
- Development and manufacturing technology for innovative improved new drugs (compound drugs)

### R&D Trends in Korea's Biopharmaceutical Sector

• Korea is prominent in the biosimilar sector, and 7 of 23 biosimilars approved by the U.S. FDA are Korean products as of August 28, 2019.

### Status of Domestic and Overseas Biosimilar Permits of Korean Companies

Company name	Product Name	Original Medications	South Korea MFDS authorization	U.S. FDA authorization	Europe EMA authorization
Celltrion	Remsima	Remicade	○(July 2012)	○(April 2016)	○(August 2013)
	Herzuma	Herceptin	○(January 2014)	○(December 2018)	○(February 2018)
	Truxima	Enbrel	○(July 2015)	○(November 2018)	○(February 2017)
Samsung Bioepis	Etoloce	Enbrel	○(September 2015)	○(April 2019)	○(January 2016)
	Remaloce	Remicade	○(December 2015)	○(April 2017)	○(May 2016)
	Adaloche	Humira	○(September 2017)	○(July 2019)	○(August 2017)
	Shampenet	Herceptin	○(November 2017)	○(January 2019)	○(September 2017)
LG Chemical	Eucept	Enbrel	○(March 2018)		
Chong Kun Dang Pharmaceutical Corp.	Nesbel	NESP	○(November 2018)		

Source: Status of permits for biosimilars in Korea (Ministry of Food and Drug Safety), U.S. (FDA) and Europe (EMA).

Note 1: Product name is licensed in Korea. The same product may have different name in different countries.

Note 2: Figures in parentheses indicate years and months of permission.



- Korea is actively researching and developing various biopharmaceuticals such as stem cell gene therapeutics, gene therapeutics, exosomes, and microbiome gene therapeutics, as well as antibody and protein medicines that form the largest market in the world.

#### Biopharmaceutical Technology Development Status

Classification	Current technology	Future development direction
Protein therapeutics	<ul style="list-style-type: none"> <li>· Target receptor binding antibodies</li> <li>· Therapeutic resistance limit</li> </ul>	<ul style="list-style-type: none"> <li>· Mutant receptor binding antibody</li> <li>· Resistance overcoming precision treatment technology</li> </ul>
Microbiome therapeutics	<ul style="list-style-type: none"> <li>· Intestinal microbial culture</li> <li>· Disease association</li> </ul>	<ul style="list-style-type: none"> <li>· Intestinal microbial artificial mass production</li> <li>· Early disease diagnosis technology</li> </ul>
Exosomes therapeutics	<ul style="list-style-type: none"> <li>· Multi-level small quantity production system</li> <li>· Disease association</li> </ul>	<ul style="list-style-type: none"> <li>· Standardized mass production system</li> <li>· Disease treatment and precision diagnosis technology</li> </ul>
Gene therapeutics	<ul style="list-style-type: none"> <li>· Gene transfer therapy</li> <li>· Genetically modified therapies through DNA cleavage</li> </ul>	<ul style="list-style-type: none"> <li>· Intrinsic genetic correction drug</li> <li>· Treatment for genetic modification without DNA cleavage</li> </ul>
Stem cell therapeutics	<ul style="list-style-type: none"> <li>· Autologous stem cell therapy</li> <li>· Adult stem cell therapy</li> </ul>	<ul style="list-style-type: none"> <li>· Allogeneic stem cell therapy</li> <li>· Customized de-differentiated stem cell therapy</li> </ul>

Source: Ministry of Trade, Industry and Energy and Korea Evaluation Institute of Industrial Technology, Industrial Technology R&BD Strategy in 2019, January 2019.

## 02 Trends of Foreign Direct Investment



## 2.1

### Foreign Direct Investment Status

#### Foreign investment statistics for bio pharmaceuticals

- As of 2017, foreign investment in the biopharmaceutical sector reached a record high of USD 350 million.
  - Foreign investment in the biopharmaceutical sector was insignificant, recording only about USD 60 million, but continued to increase, soaring to USD 350 million as of 2017.
  - In particular, investment from Europe, the Netherlands and Ireland are sharply increasing.
  - The number of investments and amount in 2018 decreased compared to the previous year. However, when combined with the investment of Company B, which has been classified as investment in another sector, the figures represent the best investment performance to date.

#### Current Status of Foreign Investment in the Bio Pharmaceutical Industry

(Unit: million dollars)

Classification	2014		2015		2016		2017		2018	
	No. of investments	Amount	No. of investments	Amount	No. of investments	Amount	No. of investments	Amount	No. of investments	Amount
America	4	3	8	14	7	23	5	30	2	-
Asia	5	56	10	84	9	26	5	1	7	23
Europe	1	-	5	25	6	215	7	321	3	1
Total	10	59	23	123	22	(264)	17	352	12	24

Source: Ministry of Trade, Industry and Energy, Foreign Investment Statistics.

Note: The USD 678 million investment of Company B, a foreign biopharmaceutical company, is not included. If included, the total investment stands at USD 702 million, which is the largest amount to date.

#### Investment of multinational pharmaceutical companies in Korea

- (R&D investment in Korea) R&D expenditure on clinical research investment in Korea by 28 global pharmaceutical companies increased by 5.9% from USD 232.4 million in 2016 to USD 246.3 million in 2017.

- (Clinical research) A total of 1,631 clinical studies were conducted in 2017 by global pharmaceutical companies in Korea, 20.5% up from 1,354 in 2016.
- (Medical research drug costs) Global pharmaceutical company's clinical research costs in Korea increased by 21.7% from USD 96.3 million in 2016 to USD 117.33 million in 2017.
- (Clinical research on cancer and rare diseases) The number of clinical studies of cancer diseases and rare diseases in 2017 was 771 and 274, respectively, and increased, compared to 507 and 79 cases in 2016.
  - The number of clinical researches of rare diseases more than tripled in 2017 compared to 2016 (27 cases).
- (R&D Research Personnel Hiring) Employment of R&D researchers in global pharmaceutical companies increased by 10.4% from 1,386 in 2016 to 1,530 in 2017.

## 2.2

### Success Cases of Major Foreign-Invested Companies

#### Supply of 1,300 domestic drugs

- Global pharmaceutical companies supply about 1,300 medicines that domestic patients need.
  - In particular, they lead the development and supply of prescription drugs, treatments for rare and intractable diseases, and vaccines, which are closely related to patients' prolongation of life.

#### Joint overseas venture

- Global pharmaceutical companies in Korea are cooperating with Korean pharmaceutical companies for overseas expansion.
  - As global pharmaceutical companies share the experience of entering the global market with Korean pharmaceutical companies, Korean pharmaceutical companies are reducing trial and error on entering the global market and they helped Korean companies successfully enter the market.

## Current Status of Joint Venture of Global Pharmaceutical Companies with Korean Companies

Foreign investment company	Korean company	Details of cooperation
Abbott	Ildong Pharmacautical	Contracted copyright for two improved drugs in Asia
AbbVie Inc.	Donga ST	Joint research on immune anticancer drug MerTK inhibitor
GSK	Dong-A Socio Holdings	Equity investment
Janssen	Hanmi Pharmaceutical	Joint development of diabetes / obesity treatment
MSD	Samsung Bioepis	Numerous biosimilar global commercialization cooperation
	Donga ST	Superbacteria Antibiotics Jointly Overseas Venture
	Hanmi Pharmaceutical	R&D Investment and Export of Combined Hypertension Treatment
Mundi Pharma	Genewell	Cooperated for overseas sale of wound dressing "Mediform"
Sanofi	Hanmi Pharmaceutical	Cooperated with technology transfer and development of continuous diabetes new drug
	LG Chemical	Cooperation on Overseas Expansion of Diabetes Treatment
Zuellig Pharma	BORYUNG Pharmaceutical	Cooperation on Overseas Expansion of Hypertension Treatment

Source: 2018 KRPIA Annual Report.

## Joint R&amp;D

- Global pharmaceutical companies in Korea are conducting a number of new drug development studies with Korean pharmaceutical companies, medical institutions, and research institutes.

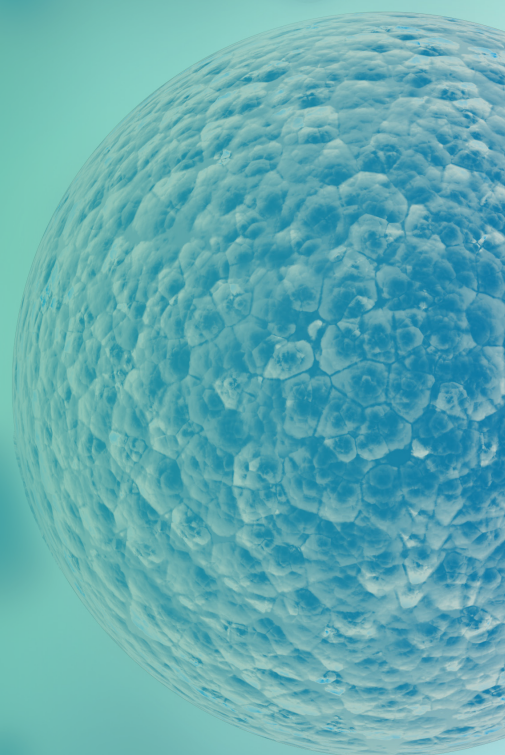
## Current Status of Joint Research of Global Pharmaceutical Companies with Korean Companies

Foreign investment company	Korean company/ institution	Details of cooperation
Abbott	Corepharm Bio	Joint development of improved new drugs
	Kolon Pharmaceuticals	Joint development of improved new drugs
Astrazeneca	Donga-ST	Joint research on leading substance of 3 immune anticancer drugs
	Samsung Biologics	Biosimilar clinical trials for blood cancer and autoimmune diseases through joint venture (Archigen Biotech)
	Korea Health Industry Development Institute	Selection and support of four anticancer mediation research projects
Bayer	KOTRA	Korea Digital Healthcare Startup Support
BMS	Samsung Biologics	Drug substance production
	Hospital	Master Clinical Trial Agreement
GSK	Yonsei University Medical School	Joint research on next-generation anticancer drugs
	Hospital	Master Clinical Trial Agreement
Lilly Korea	Korea Research Institute of Chemical Technology	Signed Partnership for Open Innovation New Drug Development
	LSK Global PS	Domestic Phase 1 clinical research on candidate substance of new drugs for stomach cancer and lung cancer
MSD	Korea Drug Development Fund	Operation of joint research and development programs related to anticancer drugs
	Pharmabcine	Joint study on combination therapy for recurrent brain tumor and metastatic breast cancer
	Genexine	Joint study on combination therapy and the drug development
Sanofi Aventis	Seoul Asan Hospital	Joint Research Collaboration on Liver Cancer Patient Bioinformatics
	Seoul National University / KAIST	Joint research collaboration on the development of next-generation immune cancer drug platform
	Institut Pasteur Korea	Joint research on development of antibiotic candidate and hepatitis B drug
Sanofi Pasteur	SK Chemical	Global joint research on next generation pneumococcal protein conjugated vaccine
		Global license agreement for the production of universal flu vaccine

Source: 2018 KRPIA Annual Report.

## 03

# Policy and location



## 3.1

### Key Policies and Incentives

Korea is expected to introduce a differential approval system for clinical trials (source: Five-year Comprehensive Plan for Clinical Trial Development, KFDA, August 2019)

- The U.S., Australia and China has reporting systems (including assumption of approval) for clinical trial plan reviews.
  - Korea has an approval system for clinical trial plans (processing period: 30 days).
- A differential approval system for safety-secured clinical trials will be introduced in stages from 2020.
  - Previously, screening was conducted uniformly regardless of the clinical stage. However, the new system applies different review methods depending on the clinical stage. For example, clinical trials are approved only with essential information such as clinical drug information.

Present		Direction of change			
Clinical trial category	Review method	Risk		Safety management	Review method
Initial term of new drug	Uniform screening (processing period: 30 days)	●	High	High ↑ ↓ Low	Intensive screening ↑ ↓ Simplified screening
Mid-term of new drug		●	Rather high		
Last-term of new drug		●	Medium		
Commercial drugs		●	Low		

- The system will initially apply to commercial drugs and multi-national clinical trials for therapeutic confirmation approved by eight drug list issuing countries including the U.S.

Serial no.	Priority introduction target
1	Pharmacokinetic and pharmacodynamics comparative clinical trials performed within the permit scope of the licensed drug
2	Multi-national clinical trial for therapeutic confirmation approved by the Drug list* issuing country * The U.S., Japan, UK, Germany, France, Italy, Switzerland, Canada (8 countries)
3	Investigator clinical trial using commercially available anticancer drugs

Source: Five-year comprehensive plan for clinical trial development, Ministry of Food and Drug Safety, August 2019

### Expansion of the scope of acceptance of nonclinical test data (source: Five-year comprehensive plan for clinical trial development, KFDA, August 2019)

- Non-clinical studies submitted at the time of application for approval of the clinical trial plan are accepted only if they meet the 'Good laboratory practice (GLP)'.
  - Non-OECD countries such as China are not allowed to submit non-clinical test data.
- When applying for a clinical trial plan, nonclinical trial data of non-OECD countries will be allowed to submit by revising the requirements of non-clinical study data submitted.

### Enforcement of high-tech biopharmaceutical related laws

- The “Act on the Safety and Support of Advanced Regenerative Medicine and Advanced Biopharmaceuticals” is scheduled to be implemented in August 2020.
  - Advanced biopharmaceuticals are biopharmaceuticals made from living cells, tissues, or genes, including cell therapy, gene therapy, and tissue engineering.
  - The Act will establish a reasonable permit review system by requiring manufacturers to advanced biopharmaceuticals by considering their characteristics distinguished from existing synthetic drugs, and establishing quality management standards.

### Support and location of foreign-invested companies

- The Korean government enacted the Foreign Investment Promotion Act to promote the attraction of foreign investment by providing foreign investors with support and convenience.

- The government continues to develop systems to encourage foreign investments with high economic contributions, such as fostering new industries including the biopharmaceutical industry and creating high quality employment.
- The government is working toward creating investment conditions that meet global standards through a reform of irrational regulations that impede free inflow of investment factors such as capital, human resources, and technology.

### Resolving grievances and communication with foreign-invested companies

- The Korean government the Foreign Investment Ombudsman Office to address and support the difficulties of foreign investors and foreign-invested companies.
  - The office handles grievance regarding labor/HR, tax, environment, finance/ foreign exchange, settlement environment, customs/customs clearance, construction and intellectual property rights.
  - The office provides foreign investors with legislative information in English and assists foreign investors in submitting comments on relevant legislative information.

## 3.2 Major Locations

### Bio Medical cluster

#### Composition Status by Major Bio Cluster

Regions	Name	Establishment period	Organizer
Chungbuk Osong	Osong Advanced Medical Complex	2009	Government
Daegu Gyeongbuk	Daegu Advanced Medical Complex	2009	Government
Seoul Hongneung	Seoul Bio Hub	2017	Local government (Seoul)
Incheon Songdo	Songdo Bio Front	2004	Local Government (Incheon)
Gyeonggi Gwanggyo/Pangyo	Gwanggyo/Pangyo Techno Valley	2005	Local government (Gyeonggi-do)

Source: Biohealth Report, Korea Health Industry Development Institute, 2019. 1

#### • Chungbuk Osong Medical Innovation Foundation

- Osong Advanced Medical Complex emerged as Korea's bio center due to the integration of bio companies along with the move-in of 6 major national health institutes in 2010.

\* 6 national institutes: Ministry of Food and Drug Safety, National Institute of Food and Drug Safety Evaluation, Korea Centers for Disease Control and Prevention, Korea Human Resource Institute for Health and Welfare, Korea Institute for Health Industry Promotion

- An organic network has been established among industry, academia, research and government, through move-in of 6 national institutes, including the Ministry of Food and Drug Safety, and the entrance of BT graduate school and cutting-edge life science companies.

#### • Daegu-Gyeongbuk Advanced Medical Complex

- Daegu Gyeongbuk Advanced Medical Complex consists of a new drug development support center, a core research facility, a high-tech medical device development support center, an experimental animal center, a clinical trial drug production center, and a communication center, which is a local government facility.
- The complex supports the development of world-class new drugs by linking basic research results with clinical stage products, and supports specialized research on synthetic new drugs by utilizing the high-quality clinical trial infrastructure of 12 clinical trial hospitals.

#### • Seoul Hongneung Biocluster

- Seoul Metropolitan Government established a network hub that will serve as a leading base for fostering related industries by utilizing the infrastructure of Hongneung area as well as facilitating the start-up of bio and medical fields.
- The Hongneung area has universities with excellent hospitals such as Korea University and Kyung Hee University, as well as comprehensive research institutes such as the Korea Institute of Science and Technology (KIST), and has favorable conditions for attracting infrastructure and excellent manpower, located in the Seoul metropolitan area.

#### • Incheon Songdo Bio Cluster

- Close to Incheon International Airport, the location includes M.Lab of Merck, Germany, which provides professional technology services to biopharmaceutical companies, and the fast track center of GE Healthcare of the U.S., for developing and training related biopharmaceutical processes.
- Focusing on biopharmaceutical production and research and development, dozens of bio-related companies are located in this Bio Cluster including Samsung Bioepis, Samsung Biologics, Celltrion, and Dong-A ST.

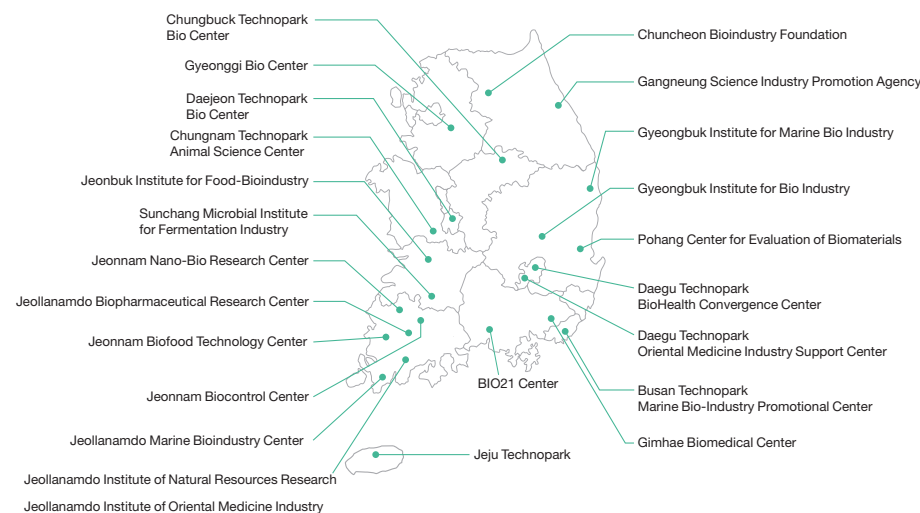
#### • Gyeonggi-do Gwanggyo/Pangyo Techno Valley

- Gwanggyo Techno Valley, located in Suwon, is a high-tech research complex established in Gwanggyo New Town. Korean companies and foreign investment companies are moving in, and university research institutes such as Ajou University, Kyung Hee University, and Seoul National University are forming a network.
- Pangyo Techno Valley is a high-tech innovation cluster located in Seongnam Pangyo New City. It's advantageous since it is located in the metropolitan area and has systematic corporate support system of Gyeonggi-do. In particular, the bio business network has formed around Korea Bio Park, where 30 bio companies are located.

### Bio Technology (BT) Specialized Centers by Region

- The Korean government is fostering local biotech companies by operating BT specialized centers in each region in order to focus on fostering bio-specialized regions and enhance national competitiveness.

#### Status of Regional BT Specialized Centers in Korea



Source: Korea BT Specialized Center Council.



## 04

## Potential Partners

## 4.1

## List of Related Companies

## Top 10 Companies in Production Performance (2018)

Company name	Main items	Website	Location
Hanmi Pharmaceutical	Hypertension treatment, etc.	www.hanmi.co.kr	Gyeonggi Province
Chong Kun Dang Pharmaceutical Corp.	Anticancer drugs, etc.	www.ckdpharm.com	Seoul
Celltrion	Antibody Biosimilar	www.celltrion.com	Incheon
Daewoong Pharmaceutical	Liver preparations, etc.	www.daewoong.co.kr	Gyeonggi Province
Green cross	Vaccines, Blood Products, etc.	www.greencross.com	Gyeonggi Province
CJ Healthcare	Asthma, Pain Relief, etc.	www.cjp.co.kr	Seoul
Yuhan Corporation	Hypertension treatment, etc.	www.yuhan.co.kr	Seoul
Donga- ST	Arteriosclerosis treatment, etc.	www.donga-st.com	Seoul
LG Chemistry	Diabetes treatment, etc.	bio.lgchem.com	Seoul

## Listed on KOSDAQ (Listed after passing technical evaluation)

Company name	Main items	Website	Location
Helixmith	Gene therapy	www.viromed.co.kr	Seoul
Bioneer	Gene drug (SiRNA based)	www.bioneer.co.kr	Daejeon
Crystal Genomics	Osteoarthritis medicine	www.crystalgenomics.com	Gyeonggi Province
Isu Abxis	Antibody Therapeutics	www.abxis.com	Gyeonggi Province
Genexine	Antibody Therapies, Vaccines	www.genexine.com	Gyeonggi Province
iNtRON Biotechnology	Antibiotics	www.intron.co.kr	Gyeonggi Province
LEGO Chem Bio	Antibody therapies, antibiotics	www.legochembio.com	Daejeon
Alteogen	Antibody Therapeutics	www.alteogen.com	Daejeon



Company name	Main items	Website	Location
Corestem	Stem Cell Therapeutics	www.corestem.com	Gyeonggi Province
Peptron	Peptide Drugs	www.peptron.co.kr	Daejeon
Eyegene	Diabetic retinopathy	www.eyegene.co.kr	Seoul
Kangstem Biotech	Stem Cell Therapeutics	www.kangstem.com	Seoul
C-TRI	Peptide Drugs	www.c-tri.co.kr	Gyeonggi Province
Anterogen	Stem Cell Therapeutics	www.anterogen.com	Seoul
Qurient	TB and Asthma Treatment	www.qurient.com	Gyeonggi Province
Pangen	Biosimilar	www.pangen.com	Gyeonggi Province
Bio Leaders	Cervical cancer treatment vaccine	www.bioleaders.co.kr	Daejeon
SillaJen	Anticancer virus treatment	www.sillajen.com	Busan
Eubiologics	Cholera vaccine	www.eubiologics.com	Gangwon-do
Olix	Gene therapy	www.olixpharma.com	Gyeonggi Province

## 4.2

### Related Associations & Organizations

#### Related Associations

Name of institution	Website	Major role
Korea Bio Association	www.koreabio.org	Central role in promoting technology development and industrialization in the Korean bio industry
Korea Pharmaceutical and Bio-Pharma Manufacturers Association	www.kpbma.or.kr	Development of Korea's pharmaceutical industry, and activities to promote the welfare of members and defend their rights
Korea Drug Research Association	www.kdra.or.kr	Enhancement of the pharmaceutical industry technology through the introduction and dissemination of advanced technologies in the pharmaceutical field

Name of institution	Website	Major role
Korea Biomedicine Industry Association	www.kobia.kr	Cooperation with the government with regard to legal system, policy, and information exchange to enhance the international competitiveness of the biopharmaceutical industry
Korea Pharmaceutical Traders Association	www.kpta.or.kr	Promotion of import and export of medicines and establishment of the distribution order
Korean Research-based Pharmaceutical Industry Association	www.krpia.or.kr	Cooperation with healthcare in Korea through rapid introduction of global new drugs, dissemination of advanced technologies and networking of global companies

#### Major Research Institutions

Name of institution	Website	Major role
Korea Research Institute of Bioscience and Biotechnology	www.kribb.re.kr	Leading the development, foundation, and commercialization of technology and platform for advanced BT
Korea Research Institute of Chemical Technology	www.krict.re.kr	Development of original technology, performance diffusion, and, operation of chemical technology public infrastructure in the field of chemical and related convergence technology
Korea Institute of Oriental Medicine	www.kiom.re.kr	Development of prevention and treatment technologies for oriental medicine to promote national health and improve the quality of life
National Cancer Center	www.ncc.re.kr	Implementation of and support for cancer research, treatment of cancer patients, support for national cancer management projects, and training of cancer specialists
Korea National Enterprise for Clinical Trial	www.konect.or.kr	Strengthening of global competitiveness by advancing clinical trials
Institute Pasteur Korea	www.ip-korea.org	Joint research with the Pasteur Institute in France and independent research Promotion of biotechnology-related research, education, and technology
International Vaccine Institute	www.ivi.int	Development and dissemination of safe and affordable vaccines for developing countries to reduce the burden on developing countries and promote public health across the world

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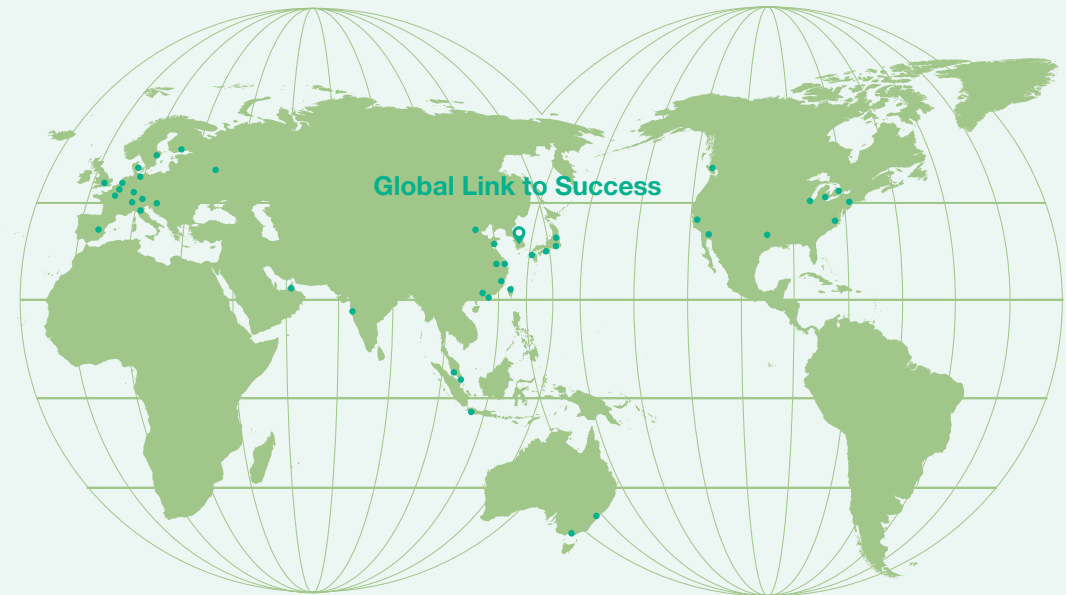
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