

# 04

## Policies and Incentives

### Tax Benefits

Based on the Restriction of Special Taxation Act, the Korean government has expanded tax benefits for investment in 11 major new industries including the biopharmaceutical sector (100% for the first 5 years and 50% for the next 2 years).

### Business Partnering Opportunities

The Ministry of Health and Welfare and The Ministry of Trade, Industry and Energy (MOTIE) annually hold "Bio Korea" and "Global Bio & Medical Forum" respectively, to provide opportunities for cooperation between Korean and foreign businesses.

### Regulatory Harmonization

Korea joined the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2014. The country also strengthened its GMP standards on par with advanced countries including the US, the EU and Japan to improve the quality of domestic products.

Moreover, Korea officially joined the International Conference on Harmonization (ICH) in November 2016, showing that Korea is recognized as an advanced country in the global medical regulatory sector.

### Governmental Support

Ministry	Description	Relevant Areas
Ministry of Science, ICT & Future Planning	Supports the medical and life science sectors in securing original technologies and transforming their research findings into practical applications	Neuroscience, genome, stem cell, etc.
Ministry of Health and Welfare	Assists clinical research in the public health and medical sectors	Medical treatment, medical products & services development
Ministry of Trade, Industry & Energy	Accelerates the R&D and industrialization process of the entire biotech industry	All
Ministry of Food and Drug Safety	Develops technologies related to the permission, approval, and evaluation of medical products and services; Supports the exports of high-tech medical products	Medical products & services development

## Success Case

BMS Korea Pharmaceutical signed OCE agreements (Oncology Center of Excellence) with major Korean cancer research institutions; produced raw pharmaceutical materials and finished drugs at a Korean factory (Songdo).

Many global pharmaceutical firms including GSK, Janssen Pharma-ceutical, Lilly, MSD, and Pfizer entered the Korean market and are actively participating in joint R&D projects with Korean researchers.

# KOTRA WORLD WIDE

As Korea's Trade-Investment Promotion Agency, KOTRA has 127 overseas offices and 10 headquarters worldwide.

\* Invest Korea(IK), Korea's national investment promotion agency, was established as part of KOTRA to support the foreign businesses in Korea.



## Headquarters

### CIS

Tel: (7-495)258-1627  
E-mail: moscow@kora.or.kr

### Europe

Tel: (49-69)2429-920/9  
E-mail: frankfurt@kotra.or.kr

### Middle East

Tel: (971-4)450-4360  
E-mail: ktcdxb@emirates.net.ae

### Africa

Tel: (27-11)784-2940  
E-mail: kotra@kotra.org.za

### China

Tel: (86-10)6410-6162  
E-mail: 712461@kotra.or.kr

### Japan

Tel: (81-3)3214-6951  
E-mail: kotratky@kotra.or.jp

### Southwest Asia

Tel: (91-124)4628-500  
E-mail: ktcdelhi@ktcdelhi.net

### Southeast Asia & Oceania

Tel: (65)6426-7200  
E-mail: kotrasin@singnet.com.sg

### South America

Tel: (52-55)5514-3173  
E-mail: mexico@kotra.or.kr

### North America

Tel: (1-212)826-0900  
E-mail: kotrany@hotmail.com

13, Heolleung-ro, Seocho-gu, Seoul, Republic of Korea (06792)

Tel: (82-2)1600-7119 Fax: (82-2)3460-7920

E-mail: ikonline@kotra.or.kr

## Head Office



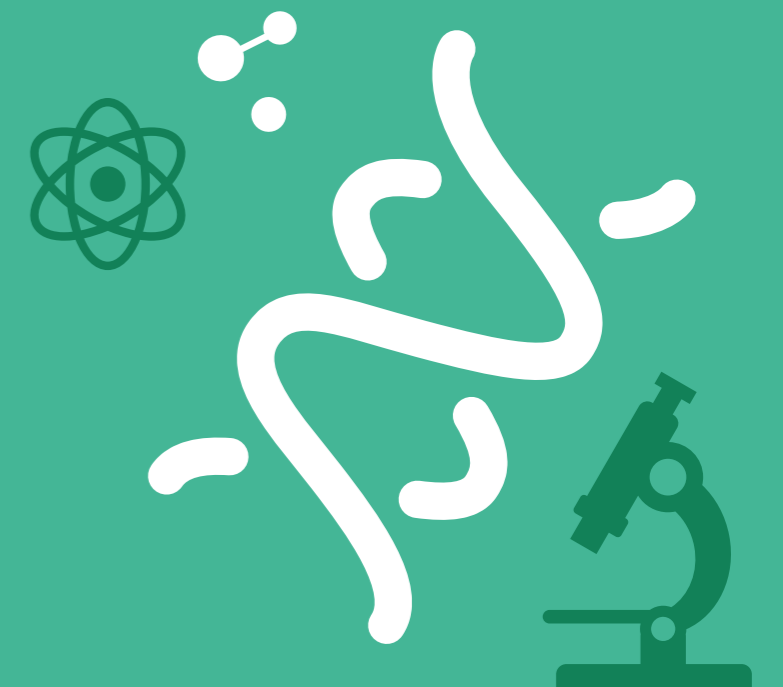
[www.investkorea.org](http://www.investkorea.org)

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KOREA'S LEADING INDUSTRIES

# BIOPHARMACEUTICAL

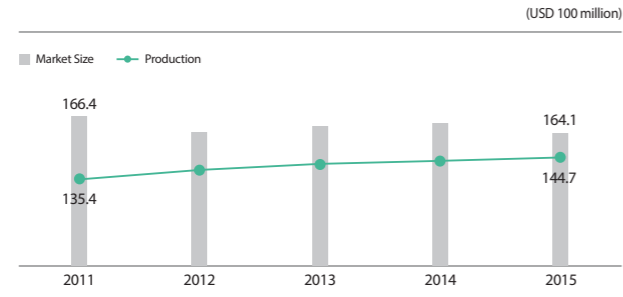


# 01

## Korea's Biopharmaceutical Industry

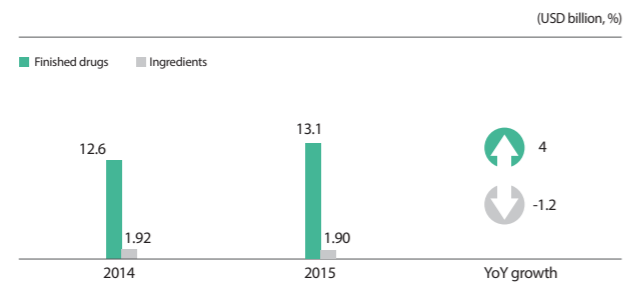
### Market and Production Size

Korea's pharmaceutical drug market amounted to USD 16.4 billion as of 2015. Its pharmaceutical drug production has steadily grown to reach USD 14.5 billion in 2015.



Source: Ministry of Food and Drug Safety, press release, 2016

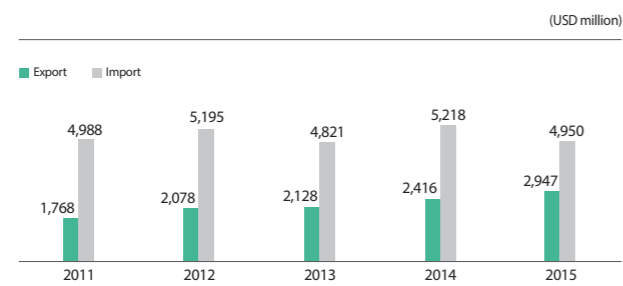
### Market Size of Finished Drugs and Raw Pharmaceutical Materials



Source: Ministry of food and Drug Safety, press releave, 2016

### Exports & Imports

As of 2015, Korea's pharmaceutical drug export volume was USD 2.947 billion, up 22% YoY. Korea's pharmaceutical drug import volume was USD 4.95 billion, down 5.1% YoY.



Source: Ministry of Food and Drug Safety, press release, 2016

# 02

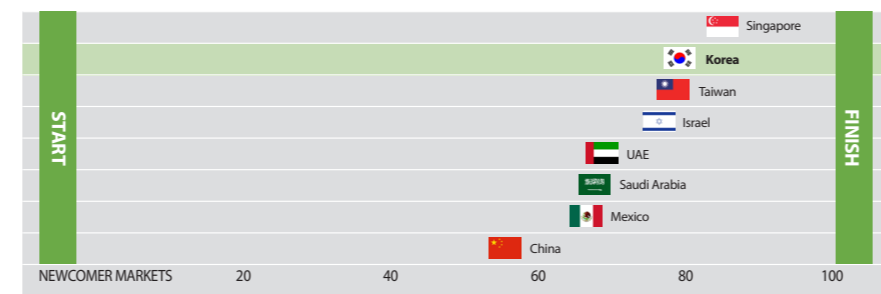
## Competitiveness

### Biopharmaceutical Powerhouse

According to the "BCI Survey" report of Pugatch Consilium, a US consulting company, Korea's BCI value was 77.94, ranking second after Singapore (85.33).

The BCI value is scored out of 100 based on five areas (science/technology/infrastructure, clinical research performances/environment, regulatory system/drug approval, quality assurance/drug surveillance, market entry/financing, IP right protection).

### Competitiveness of Biopharmaceutical Companies in Emerging Countries in terms of innovation



Source: Biopharmaceutical Competitiveness and Innovation (BCI) survey, 2016

### New Drug Development

Korea's biopharmaceutical industry has steadily expanded investments in the R&D sector to develop blockbuster drugs. A total of 27 domestically-developed new drugs gained approval until now. In 2015 alone, five new drugs were approved.

According to the 2014 survey of 36 innovative pharmaceutical companies, a total of 785 new drug development projects were underway including 330 new chemical synthetic drugs, 354 new incrementally modified drugs and 131 original biological products.

### Biosimilar Development

Korea was elected as a chair of the Working Group on Biosimilar Regulatory Harmonization at the International Pharmaceutical Regulators Forum (IPRF) in 2013.

Remsima, the world's first biosimilar antibody manufactured by Celltrion Inc. of Korea gained approval by European Medicines Agency (EMA) in July 2013 and by the US FDA in April 2016.

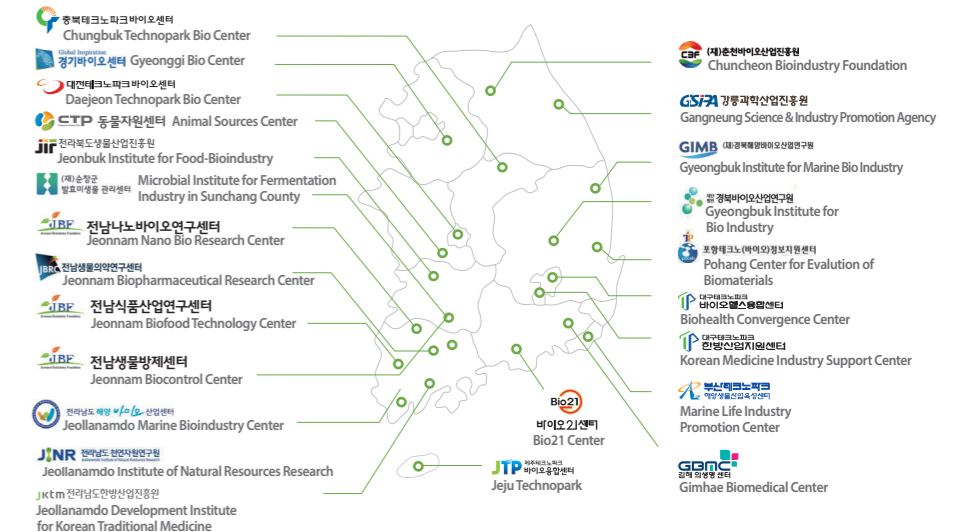
Biosimilars of Samsung Bioepis, including Benepali, Flixabi and Lusuduna received marketing authorization from the European Medicines Agency (EMA) in January 2016, May 2016 and January 2017, respectively.

# 03

## Industry Clusters

### BT-Specialized Clusters

The Korean government has operated biotech-specialized centers in several regions to create large-scale biotech clusters. By growing biotech-specialized regions, it ultimately seeks to boost national competitiveness.



### Osong High-Tech Medical Complex

The Osong Complex has forged a network that connects industries, universities, research and public institutions, on the back of the relocation of six major public institutions (including the Ministry of Food and Drug Safety), BT-specialized universities and companies.

### Daegu/Gyeongsangbuk-do High-Tech Medical Complex

The Daegu/Gyeongsangbuk-do Complex has an excellent infrastructure that includes several core research facilities of the government (New Drug Development Center, High-Tech Medical Device Development Center, Animal Testing Center and Clinical Trial & New Drug Production Center) and 12 hospitals that carry out clinical trials.

### Gwanggyo/Pangyo Techno Valley (Gyeonggi-do)

Gwanggyo/Pangyo Techno Valley is a state-of-the-art convergence hub of IT, BT, CT, and NT businesses, which is characterized by its proximity to the capital area and comprehensive business support by the local government. A total of 200 Korean and global investment companies, as well as the research centers of Ajou University, Kyung Hee University and Seoul National University are located in the complex.