Healthcare Industry in Korea

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Overview - Demographics

- Population (S. Korea): 50.4 Million (2013)
- Average life expectancy: 81.4 [M: 77.9, F: 84.6] (2012)
- Elderly population: (65+years) 12.7% (2013)
- Male vs Female: 105.7:100 (2012)
- Geographic distribution: More than 60% located in Seoul and the 5 largest cities

Overview- GDP & Total Healthcare Expenditure

- Korea's GDP per capita in 2013 was around USD 24,000.
- Korea spent 7.6% of GDP; Among 34 OECD countries, it ranked 26th in spending in terms of percentage of GDP to healthcare.

Overview - Korean Healthcare System

- **Korea has compulsory National Health Insurance (NHI) System :**
  - National single payer system in Korea
  - Introduced in 1977
  - Has covered entire population from 1989*
  - Government administers funds, coverage, coding, payment and pricing

Healthcare market - Pharmaceuticals

- Korea's total market for drugs and pharmaceuticals in 2014: approximately USD 16 billion.
- Multinational company (MNC) sales: approximately 30-35% of the overall market.
- Domestic Korean firms are strong in the manufacturing of generics, rather than innovative drugs. The Korean Government would like to change this.
- South Korean pharmaceutical companies are open to innovation and have begun to develop technologies with MNCs.

Regulatory requirements for pharmaceuticals

- Ministry of Food and Drug Safety (MFDS) is the regulatory authority : supervises and manages regulatory licenses, implementation of quality management and post-market surveillance, etc.

- All domestic and foreign pharmaceutical products must have a pre-market license from the MFDS, regardless of whether the product is on patent, new-to-market chemical entity or an off-patent generic

- MFDS also requires a local importer to do local quality testing for each shipment whenever it arrives in Korea.

- MFDS issues product licenses only to locally based firms.

- All foreign suppliers must submit required documentation and receive necessary approvals through a Korean importer or a Korea-registered subsidiary of the US supplier.

Healthcare market – Medical devices

- Total medical device market (2013): USD 4.2 Billion

  - Local production: USD 3.9 Billion
  - Imports: USD 2.7 Billion
  - Exports: USD 2.4 Billion

➢ Korea imports:
  – High-end and expensive medical devices mostly from the U.S., EU and Japan (supplying about 65% of total market demand).

  – U.S. is the largest foreign device supplier accounting for about 45% of the import market.

  -- Low tech devices from countries like China.

➢ Korean manufacturers supply mid-tech devices.

Medical Device Market –
Top 10 Volume Foreign Medical Devices (2013)

- Soft contact lenses
- Stents
- MRI System
- Kidney dialysis devices
- CT system
- Knee implants
- Lenses for eye glasses
- Ultrasound imaging system
- Intraocular lenses
- Catheters

Regulatory Requirements for medical devices

- All domestic and foreign medical devices are subject to pre-market licenses from the Ministry of Drug and Safety (MFDS, formerly KFDA).
- Medical devices are classified into four categories in Korea.
- MFDS requires pre-market notification for class 1 devices and pre-market approval for class 2, 3 and 4 devices.
- Class 3 and 4 devices must pass the most stringent technical review by a MFDS authorized lab to prove product safety and effectiveness.
- Also, as of April 8, 2012, KGMP certification is required at manufacturers' sites overseas (Class 3 and 4) or in Korea through their importers by documents (Class 2), depending on cases and criteria.

Healthcare Trends (I)

- Korea is the fastest aging country in Asia.
  - Market, price, regulations and consumer awareness are changing.
  - Cancers, chronic diseases and immune diseases are increasing.
    - ➢ Estimated demand for oncology products approximately USD 600 million.
    - ➢ Increased demand for biopharmaceuticals for personalized medicines, such as for immune diseases.

Healthcare Trends (II)

Economic Challenges

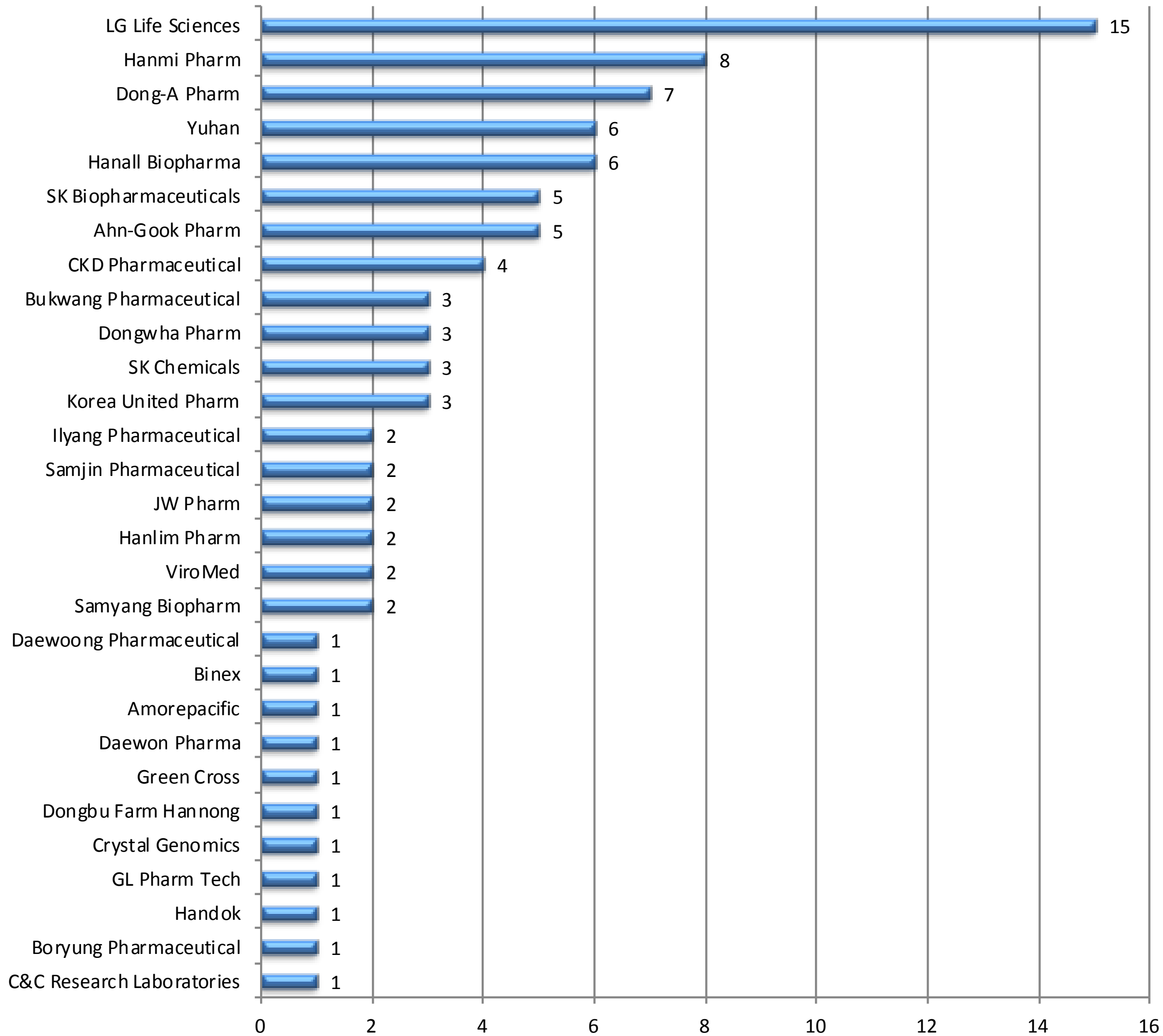
- The healthcare cost that the Korean government has to pay under the Korea's NHI System is increasing.
- Recently, Korean government has announced plans to develop the "Creative Economy."
- Development of the local healthcare industry is a focus as one of the Creative Economy sectors
- Major healthcare growth engines include:
    - Production of higher grade of medical devices
    - Development of biosimilars
    - Medical tourism (to Korea)
    - (to attract) clinical trials to Korea.

Opportunities in Korea

Given trends, foreign healthcare companies may have good potential in:

- Therapeutic drugs for cancers, chronic diseases
- High-end medical devices
- Combinations of drugs and medical device (e.g. DES, drug balloon, etc.)
- Clinical trials
- Collaboration on biosimilar drugs (R&D, manufacturing and sales)

Status of Technology Licensing-out to 26 countries



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Source : Korea Drug Research Association, 2012

Barriers to entry into Korea

- **National Health Insurance Program and Reimbursement Pricing**

-NHI system is administered by Ministry of Health and Welfare and is operated by both Health Insurance Review Assessment/Service (HIRA) and National Health Insurance Service (NHIS).

-Long-standing pricing and reimbursement issues continue to present challenges to U.S. healthcare companies operating in Korea.

- **Tariffs**

Due to the Korea-U.S. Free Trade Agreement (KORUS FTA) implemented on March 15, 2012, approximately 85-90 percent of imported medical devices in Korea became duty-free within the first year, and tariffs on the rest will be eliminated over five years.

Life Sciences in Korea

Major areas of the life sciences industry in Korea are bio pharmaceuticals, specifically biosimilars, and stem cell therapy products.

- Biopharmaceuticals have the largest share of the Korean biotech market.

- Korea has four Stem Cell products approved by the government,
  - its market is in early stage of commercialization and the market is small currently.

Life Sciences– Biopharmaceuticals

- Total Market Size: Estimated at about USD 1.6 billion in 2012
- Compound Annual Growth Rate (CAGR): approximately 15% (2006-2012)
- Prospective market for foreign and Korean firms
  - Therapeutic antibody drugs
  - Vaccines

(Major Korean companies manufacturing bio drugs include: Green Cross, LG Life Sciences, Dong-A Pharm, CJ HealthCare)

Source: Korea Biomedicine Industry Association

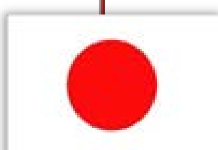
Life Sciences – Stem Cell product

- Market size (2012): USD 500 million.
- Four stem cell therapy products approved in Korea
- Market is small currently (for several reasons):
    - early stage of commercialization
    - clinical evidence is not solid
    - not commonly used yet without clinical data
    - expensive price (non-reimbursable under NHI)

Biosimilars approved

No	Brand name	Company	Drug Substance	Reference	Approval Date
1	Remsima	CELLTRION	Infliximab	Remicade	2012. 07. 20

No	Reference	No. of products	Company	Approval Year
1	Somatropin	1	Sandoz	2006
2	Epoetin alpha	3	Sandoz, Haxal, Medice	2007
	Epoetin zeta	2	Hospira, Stada	2007
3	Filgrastim	6	Ratiopharm etc.	2008~2010
4	Infliximab	2	CELLTRION	2012



No	Reference	No. of products	Company	Approval Year
1	Somatropin	1	Sandoz	2009.6
2	Epoetin alfa	1	JCR	2010.1

No	Reference	Company	Approval Year
1	Etanercept	Cipla	2013. 4

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Source : Korea Health Industry Development Institute (KHIDI), March 2014

Approval Status of Korean Stem Cell Therapies

	Company	Product Name	Category	Indication	Approval Date
1	**PHARMICELL**	**Hearticellgram-ami**	Autologous Bone Marrow derived MSC	Acute myocardial infarction throug h intracoronary injection	2011 July
2	**MEDIPOST**	**Cartistem**	Allogeneic umbilical cord blood derived MSC	Traumatic and Degenerative Osteoarthritis	2012 January
3	**ANTEROGEN**	**Cupistem**	Autologous Adipose Tissue Derived MSC	Crohn's fistula	2012 January
4	**CORESTEM**	**Neuronata-R**	Autologous Bone Marrow derived MSC	Amyotrophic lateral sclerosis (ALS) (Also known as Lou Gehrig's disease)	2014 July

Source : Korea Biomedicine Industry Association (KOBIA), 2014

Thank you!

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