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KFDA

Global Development : Korea's Perspective and the role of KFDA

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1. Current Status and Outlook of Global Pharmaceutical Market

A. World Pharmaceutical Industry

- Global pharmaceutical market size in ’05
  - 602 trillion KRW with 10% annual growth rate
- Steady growth is expected
  - Expected to be 900 trillion KRW by 2010

Global Pharmaceutical Market (in trillion)

	1998	1999	2000	2001	2002	2003	2004	2005
Global Market (KRW)	298	331	356	390	427	497	559	602
Growth Rate	7%	11%	11%	13%	9%	10%	8%	7%

Sources: IMS health, IMS MIDAS, Quantum

B. Market Status in Major Regions

- Market leaders
  - U.S.A. with 45% of global market share
  - Europe: Germany, France, England, and Italy
  - Japan with 11% of market share, 60 trillion KRW
  - China with the highest growth rate: 30%

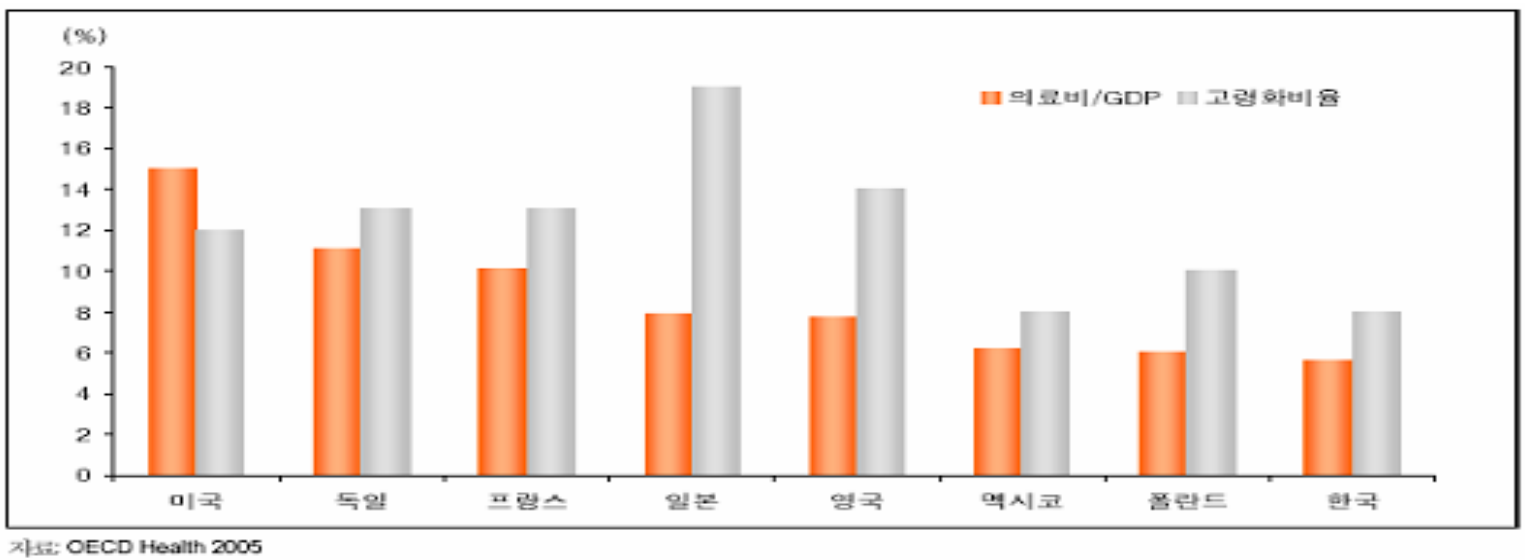
Market Share Status in 2005

Country	Market Size (trillion KRW)	Market Share (%)	Growth Rate for Past 12 month (%)
U.S.A.	246.4	44.7	7
Germany	31.2	5.7	6
France	30.3	5.5	7
England	20.3	3.7	3
Italy	19.4	3.5	0
Japan	**60**	**10.9**	**3**
China	**17**	**2.8**	**30**

Japan : 11 of world's 50 largest companies, such as Takeda
China : Fast market growth (**Increased 28% from 2004 to 2005**)

C. Outlook

- Steady increase of medical expenses:
  - The price of medicine, due to the aging society
  - Spread of well-being trend, improvement in quality of life as household income increases
  - Expanding demand in Quality of Life Drug for chronic diseases such as obesity, hypertension, erectile dysfunction, and diabetes
- Expects rapid growth of natural substance based drugs, due to the expansion of preventive and alternative medicine usage



자료: OECD Health 2005

2. Pharmaceutical Industry in Korea

A. General Status

- When compared with GDP, Korea's medical expense is lower than other OECD members (6%)
  - Compared with medical price, it is the highest (28%)
- With increase of income and change of life style, Korean pharmaceutical market is pursuing Quality of Life Drug, like other developed countries

B. History of Domestic Pharmaceutical Industry

- Secured medical technology in 1960's
- Established domestic drugs from materials in 1970's
- Started to develop new drugs in late 1980's
- Development of antibiotics was major focus until 90's
- Development of geriatric drug after 2000
- Hereafter, to enhance the quality of life, obesity, alopecia, and erectile dysfunction drugs will be the major development of domestic pharmaceutical industry.

History of New Drug R&D in Korea

Antibiotics (1980's ~ 1990's)	Drugs for diseases caused by living habit (1990's ~ Present)	QOL Drugs (2000's and after)
Decrease of antibiotic 1980's: 20% 2001: 15% Due to brief treatment period for antibiotics, they have shorter expiration date	Transition from infection treatment drug based market to chronic and geriatric drug based market (Larger emphasis on chronic and geriatric diseases, such as hypertension and diabetes)	To follow current life trend, rapid growth of QOL drugs, rather than life related drugs Along with growth of technology, vast possibility of development of erectile dysfunction, obesity and alopecia drugs

C. Market size and its structure

- Total production of domestic drug market: 9.6 trillion KRW in 2004, 11.3 trillion KRW in 2006 (Actual product sales)
  - 1.3% of GDP
  - 1.8% of global market, 11th largest market and rapidly growing.

Domestic Market in Global Pharmaceutical Market

Year	2000	2001	2002	2003	2004
Share	2.2%	1.8%	1.8%	1.7%	1.8%

Sources: Global market, IMS Health, 2005; Korean market, actual product sales in Korea pharmaceutical manufactures association, 2005

D. Development of New Drugs

- Major development of new drugs after introduction of “Material Patent System” in 1987
  - “Sunpla inj.” (SK Pharmaceuticals, ‘99) First domestically developed drug
  - “Factive” (LG Life Science) FDA approved (April, ‘03)
  - As of 2007
    - Total of 15 drugs were domestically developed and about 40 technologies exported.
    - Clinical trial for new drugs: about 30 cases
    - Pre-clinical trial in process: 25 cases
- With approval of FDA (U.S.A.), 5~6 new drugs are in clinical trials

New Development Projects for Major Korean Companies

Products	Stages		# Products	# Companies
New Drugs	Clinical Trial	Phase I	7	7
		Phase II	11	9
		Phase III	12	7
	Preclinical		50	25
	Discovery		28	14
Others	New formulations /Combinations /DDS		75	33
	Biotech Medicines		26	16

Achievement of New Drug R&D in Korea

No.	Product	Company	Indication / Efficacy	Approved date
1	Sunpla injection	SK chemicals	Stomach cancer	Sep. 1999
2	EGF topical solution	Daewoong Pharm. Co., Ltd.	Diabetic antiulcerant	May. 2001
3	Milican	Dong Wha Pharm.	Anti Liver Cancer	July. 2001
4	Q-roxin Tablet	ChoongWae Pharma Corporation	Urinary infection	Feb. 2001
5	**Joins Tablet**	**SK chemicals**	**Antiarthritis**	**July. 2001**
6	**Stillen Capsule**	**Dong-A Pharm. Co.,Ltd.**	**Gastritis**	**June. 2002**
7	Factive Tablet	LG Life Sciences Ltd.	Antibiotic	Dec. 2002
8	**Apitoxin**	**GuJu Pharm. Co., Ltd.**	**Antiarthritis**	**May. 2003**
9	Pseudovaxin injection	CJ	Pseudomonas aeruginosa	May. 2003
10	Camtobell injection	Chong Kun Dang Pharm. Corp.	Anticancer	Jan. 2003
11	Revanex Tablet	YUHAN Corporation	Antiulcer	Sep. 2005
12	Zydena Tablet	Dong-A Pharm. Co.,Ltd.	Erectile Dysfunction	Nov. 2005
13	Levovir Capsule	Bukwang Pharm.Co.,Ltd.	Hepatitis B	Nov. 2006
14	Mvix Tablet	SK chemicals	Erectile Dysfunction	July. 2007

※ Joins Tab., Stillen Tab., and Apitoxin have been classified as natural substance based drugs, and have been excluded from cell treatment

E. Infrastructure of Clinical Trials

- Established “Good Clinical Practices” in December 1987
- Mandatory in October, 1995
  - Adopted ICH GCP standard in Jan. 2000, reinforced subject’s right, its safety protection and the liability of the testers
  - IND (Investigational new Drug Application) became effective in dec. 2002, establishing the founding stone of Global Harmonization
- Total 16 preclinical testing facilities (GLP appointed) for new drug development, and 3 facilities with ability to conduct all stages of the test
- Clinical trials is conducted in 119 institutions

Current Status of Preclinical Trial October 2008.3

NO	SITE
1	KOREA INSTITUTE OF TOXICOLOGY
2	YUHAN RESEARCH INSTITUTE
3	LG LIFE SCIENCES RESEARCH INSTITUTE
4	BIOTOXTECH
5	OCCUPATIONAL SAFETY AND HEALTH RESEARCH INSTITUTE
6	CHEMON PRECLINICAL RESEARCH CENTER
7	AMOREPACIFIC R&D CENTER
8	CLINICAL RESEARCH INSTITUTE SEOUL NATIONAL UNIVERSITY HOSPITAL
9	KOREA TESTING & RESEARCH INSTITUTE
10	MEDVILL
11	BIOCORE
12	IBIOPHARM
13	CENTER FOR BIOSAFETY CATHOLIC UNIVERSITY OF DAEGU
14	CLINICAL RESEARCH INSTITUTE DONGA UNIVERSITY MEDICAL CENTER
15	SEOUL PHARMA LABORATORIES
16	KOREA ENVIRONMENT & MERCHANDISE TESTING INSTITUTE

- Established global level infrastructure of clinical trials, along with active development of new drugs and discovery of replacement drugs by the pharmaceutical companies and new venture life science firms
  - With the increase of global clinical trials, domestic trials also increase rapidly

Clinical Trial Status (Numbers of Practice)

	2001	2002	2003	2004	2005	2006	2007
Total	45	55	143	136	185	218	281
Domestic Trials	27	38	97	75	90	110	134
Others	18	17	46	61	95	108	147

New Drug Development Cases in Korea(1)

- Small molecules, approved by FDA

  - Brand name : Factive tablet/Tablets (Ethical drug)
  - Company : LG Life Science
  - Active Ingredient : gemifloxacin mesylate
  - Indication : synthetic broad-spectrum antibacterial agent
  - Dosage & Administration :

    Acute bacterial exacerbation of chronic bronchitis :
    DOSE-One 320mg tablet daily / DURATION-5 days
    Community-acquired pneumonia :
    DOSE-One 320mg tablet daily / DURATION-7 days

New Drug Development Cases in Korea(2)

- Success of natural substance based development, derived from traditional medicine

  - Brand name : Stillen Capsules/Tablets (Ethical drug)
  - Company : Dong-A Pharmaceutical.
  - Active Ingredient : Extract of Artemisia princeps 60mg
  - Indication : Gastrointestinal diseases
    (Gastritis, Prevention of gastritis by NSAID)
  - Dosage & Administration : 1Tab. Three times daily
  - Sales : 60 billion KRW in 2007

3. Assessment of Korea's New Drug Development

- One new product every year since 2000
  - Products are mostly sold in domestic market
  - Drugs based on natural substances are more compatible than chemical based
- New drugs are developed from initial research stages and showed maximization of potential for successful development
  - There are limits due to its prolonged time and high risk
  - Most of the projects in initial research stages are funded by the government
- Infrastructure of clinical test has been evaluated to have global competitiveness
  - Infrastructure needs to be expanded for continuous development of new drugs

- **To contribute to Asian's health and the region's economic growth, through maximizing Korean pharmaceutical industry's strength and complementing its weaknesses**

- **From a future-oriented and a long term point of view, Korea, China and Japan need to establish their cooperation by amplifying their similarities and the strengths**

4. Direction of Global Development with Korea, China and Japan

A. Establish a system to deliver new drugs to the patients immediately among the three nations

B. Differentiate from U.S.A., Europe and Japan centered ICH, and shape Global Development with enhanced regional characteristics

- Recognize the differences among countries, but suggests that its direction of pharmaceutical industry of the three countries while presenting a future plan
- Develop a plan to utilize geographic proximity, cultural and ethnic similarity for global development of science

- For global harmonization, Korea has implemented regulations regarding clinical and preclinical trials, authorization (IND, NDA) and production (DMF, GMP) to amend ICH's suggested guidelines for quality, safety and validity.

- Korea has announced "Development of the Pharmaceutical Industry as a New Growth Power" as a government project, promoting global harmonization of the pharmaceutical industry.

6. Role of KFDA

① Continual pursuit of global harmonization: implementation of ICH guidelines
- Introduced ICH GCP (Currently enforced)
- Introduced OECD GLP standard (Currently enforced)
- DMF system, upgraded cGMP standard (Currently enforced)
- Introduced CTD system (Plan to enforce in March ’09 with new drugs)

② Discovery of Eastern Values: Focus of Korea, China and Japan’s cooperation
- Develop plan to reflect Eastern values such as natural substa nce, herbal medicine, etc.
- Reflect Asian experience through cooperation of Korea, China, and Japan

③ Share technology and experience centered Asian clinical trial

- Participate in expedited new medicine development through cooperative clinical trial among Korea, China, and Japan in order to provide a scientific explanation for differences in ethnicities

④ Cooperation for holding a joint seminar among Korea, China, and Japan pharmaceutical associations and regulatory organizations

⑤ Operate a Korean professional group to seek Korea, China, and Japan cooperation plan through a Korean professional group

- Herbal and natural substance medicine division
- Korea, China, and Japan cooperative clinical trial, cross-bridge division
  - Search for scientific explanation for ethnic differences
- Review Process division
- Regulation and system harmonization division

Thank You