

A Study on the Problem and Improvement of the Distribution System of Pharmaceuticals in Korea

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Abstract

The purpose of this study is to examine the development of the pharmaceutical distribution industry. The pharmaceutical industry is expected to suffer a heavy blow when the Free Trade Agreement (FTA) is introduced, despite its best efforts. Therefore, adequate solutions must be found.

Section II introduces the Korean pharmaceutical distribution system and its current situation; Section III explores the distribution system's strengths and weaknesses. Section IV, identifies the problem and possible solutions for the Korean pharmaceutical distribution system; Section V summarizes and concludes this paper and acknowledges its limitations.

Finally, this paper has a clear limitation. The lack of objective information and scientific analysis due to the data being based on interviews with company representatives is its most significant shortcoming. However, it offers implications for new directions for future research.

Keywords : Korean pharmaceutical distribution, distribution structure,

JEL Classifications : I11, M31, O14, O41.

I. Introduce

Unlike other products, medicines will affect the life and health. Because of the production, distribution, and consumption are regulated strictly by law. Also it is different to follow the professional doctor or pharmacist prescription.

Because of the many pharmaceuticals distribution problems, the government and the pharmaceutical wholesalers had do several efforts to overcome these problems.

Although the government also implemented centralization in order to save the Wholesalers, but the centralization was abolished in finally for the hospitals and pharmaceutical companies' against.

In addition, the government established dual punishment system for

canceling the rebate in 2010 year in order to solve the pharmaceuticals wholesalers disorderly and the opacity problems. And the government will implement RFID until 2015 year for establishing transparent distribution structure.

Korean pharmaceuticals Industries are expected to reduce the benefit from the March 15, 2012 effectuation of the Korea-U.S. free trade agreement or KORUS FTA

Particularly problematic is a system linking patents and the approval-patent linkage system was originally designed in order to protect patents' right. The patent owner shall be notified of the identity of any other person who requests marketing approval to enter the market during the term of patent. Consequently, this provision indicates that any pharmaceutical company which makes generics cannot have the permission of marketing its generics without approval of patent owner.

Under this system, Korean firms to produce generic drugs to the US companies that hold the relevant patents. US companies could then file patent infringement lawsuits. This would mean that pharmaceutical companies intending to produce the generics must receive confirmation from the patent holder that the patent has expired, or win a legal case (Korea Health News, 2012).

The purpose of this study is to research hopefully the pharmaceutical distribution industry development. Although putting a lot of efforts, but when the FTA enters into force, the pharmaceutical industries are expected to take a heavy blow. Therefore we must find to take corresponding solutions.

In this paper: Section II, give an introduction of the Korean pharmaceutical distribution system and current situation Sections III, explore the distribution system of strengths and weaknesses. Section IV, On the basis of Sections III, find to the problem and take efficiency corresponding solutions in Korean pharmaceutical distribution system Section IV, summaries this paper and concludes the features and the limitations.

II. Pharmaceuticals distribution and Domestic current Status

1. Literature review on the pharmaceutical distribution

The pharmaceutical distribution systems of literatures are not much unexpectedly. So the center of represent discussions can be summarized as follows.

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<Table 1> Literature review

Researcher	Literature
Jung (2006)	Improvement of Distribution by Drug Information Center in Korea
Kwon et al.(2007)	A Study on Distribution System of Pharmaceuticals in the Korea
Ko (2008)	The object on Distribution System of Pharmaceuticals in order to advance
Youn et al. (2008)	A Study on Inter grated Physical Distribution of the Pharmaceutical Industry in Korea
Im (2008)	Examination of introducing and promoting the RFID system to ensure transparent and advanced distribution of pharmaceutical products
Kwon (2009)	A study on pharmaceutical item distribution and its improvement in Korean market

Jung (2006) this study results as follow : 1) Establishing central and local distribution centers to protect overlapping business.2) Introducing bar-code system for tracking drugs. 3) Introducing drug purchasing card to protect illegal deal among company, distributor and medical organization.

Kwon et al.(2007) this study examined state of local pharmaceuticals industry and investigated distribution system. The study found out associated problems as well as improvements of distribution system of local pharmaceuticals. Finally, to improve distribution system of local pharmaceuticals, the study investigated distribution system of 10 kinds of pharmaceuticals of 'J' Company being a leading local manufacturer of local pharmaceuticals, and found out improvements of the distribution system. The study collected and compiled 'J' Company's internal slips and reporting material from April 1, 2008 to July 31, 2008, and interviewed persons in charge continuously to find out state and problems of the distribution system.

Youn et al. (2008) this study summarized the Korean pharmaceutical industry needs an integrated distribution system. Considering characteristics of the Industry, however, the small pharmaceutical companies are thought to be difficult to accept the integrated distribution because complete integrated distribution may reduce sales.

Kwon (2009) this study was conducted to examine Korea's pharmaceutical item distribution conditions and systems and propose measure to improve the distribution structure by solving the existing problems for transparency and fairness and to develop the pharmaceutical Industry.

Im (2008), this researcher designed a study to: examine the effectiveness of introducing the RFID system, a new international trend reflecting the industry's efforts to keep pharmaceutical distribution transparent and to achieve advancement in the distribution; and find out the ways to promote the RFID system in local settings.

The problems of the pharmaceutical distributions are similar as described above researchers also. But the perspective is slightly different and distinguish the various forms could be seen.

Therefore, this study refer to an existing discussion, On the basis of the problem of pharmaceutical distribution in new idea, the distribution system of strengths and weaknesses and the internally and external environment is divided to analyze problems.

2. The definition of drug

Drug according to the Korean pharmaceutical affairs law Article 2 paragraph 4 is defined as follows. The term "drug" means a product falling under any of the following subparagraphs:(a) Those, other than quasi-drugs, among products listed in the Korean Pharmacopoeia;(b) Products used for the purposes of diagnosis, medical care, alleviation, treatment or prevention of diseases of human beings or animals, excluding appliances, machinery and equipment;(c) Products, other than appliances, machinery or equipment, used for the purpose of exerting pharmacological effects upon the structure or functions of human beings or animals (Korea College of Pharmacy Council,1996).

3. The definition of Distribution of Drugs

The Korean pharmaceutical affairs law Article 44is defined as follows. (1) No person, other than pharmacy founders (including pharmacists or oriental pharmacists working for such pharmacy; hereafter the same shall apply in Articles47, 48 and 50) shall sell drugs or acquire drugs for sale: However, the same shall not apply in cases where a person who has obtained product approval or an importer of drugs sells drugs manufactured or imported to a person who can manufacture or sell drugs according to this Act. (2) Notwithstanding the provisions of paragraph (1), any of the following persons shall be eligible to sell drugs or acquire drugs for sale:1. Korea Orphan Drug Center established pursuant to Article 91; 2. Herb druggists or drug wholesalers permitted pursuant to Article 45. <Amended by Act No. 8643, Oct. 17, 2007>

4. Licenses of Drug Distribution Business

(1) A person who intends to become a herb druggist or drug wholesaler pursuant to Article 44 (2) 2 shall be licensed by the head of a Si/Gun/Gu, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall apply to the modification of the licensed matters. <Amended by Act No. 8852, Feb. 29, 2008; ActNo. 9932, Jan. 18, 2010>

(2) A person who intends to obtain a license pursuant to paragraph (1) shall have the facilities meeting the standards of facilities prescribed by Presidential Decree.

(3) A license of a herb druggist pursuant to paragraph (1) shall be granted to a person who has passed a herb druggist examination prescribed by Presidential Decree by limiting districts prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(4) A herb druggist who has obtained a license pursuant to paragraph (1) may sell herbal materials after mixing them in accordance with a prescription recorded in an established herb book or with a prescription of an oriental pharmacist.

(5) A drug wholesaler who has obtained a license pursuant to paragraph (1) shall employ a pharmacist and have him/her administer duties, and a herb wholesaler shall employ any of the following persons and have him/her administer duties : However, in cases where the drug wholesaler who himself/herself is a pharmacist administers duties in person, or the herb wholesaler who falls under any of the following subparagraphs administers duties in person, this shall not apply : <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>

(6) When a drug wholesaler or herb wholesaler intends to employ a person who administers duties under paragraph (5), he/she shall report to the head of a Si/Gun/Gu, as prescribed by Ordinance of the Ministry of Health and Welfare.

(7) Matters necessary for the standards, conditions and management of approval pursuant to paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010; Act No.10788, Jun. 7, 2011>

III. Status of drug Market in Global and Domestic

1. Domestic Market

Statistical Yearbook 2011 published by Korea Food & Drug Administration, according to the pharmaceutical industry by 2010, Total domestic pharmaceutical production amount Output in 2010:15 trillion and 709.8billion won in total (\$13.5 billion and 87 million)and 6.2% year-on-year increase rate. And Domestic market size amount in 2010:19 trillion and 143.7 billion won in total (\$16.5 billion and 57 million) and 5.1% year-on-year increase rate.Exports amount Output in 2010: 1 trillion and 988.3 billion won in total (\$1.7 billion and 19million) and 11.0% year-on-year increase rate.

<Table 2> Trade balance and market size of domestic pharmaceutical products : 2006-2010

Unit : 100 million won, %

Classification	2006	2007	2008	2009	2010	Year-on-year increase rate
Production amount	114,728	125,982	138,938	147,886	157,098	6.2
Market size	140,707	152,635	171,854	182,206	191,437	5.1
Exports	8,711	9,554	12,666	17,872	19,833	11.0
Imports	34,690	36,207	45,582	52,193	54,172	3.8
Trade balance	-25,979	-26,653	-32,916	-34,321	-34,339	-0.1

Source : KFDA(2011a)

Imports amountOutput in 2010: 5 trillion and 417.2 billion won in total (\$4.6 billion and 85 million) and 3.8% year-on-year increase rate.Trade balance amount Output in 2010: to reduce 3 trillion and 433.9billion won in total (\$2.9 billion and 69 million) and -0.1% year-on-year increase rate.

Domestic pharmaceutical production amount Output in drug products: 14 trillion and 234.7 billion won in total (\$12.3 billion and 11 million) and Exports amount: 914.9 billion won and Imports amount: 2 trillion and 913.9 billion won. Degree of self - support for drug products in 80%.Domestic pharmaceutical production amount Output in drug substances:1 trillion and 475.1 billion won in total (\$1.2 billion and 75 million) and Exports amount: 855.1 billion won and Imports amount: 2 trillion and 195.0 billion won.Degree of self-support for drug products in 20% (KFDA, 2011a) .

Top 5 companies account for 33.5% of the total manufacturing output in 2008, Pharmaceutical Company of Dong A (1st), Hanmi (2nd), Daewoong (3rd), Handok (4th), Yuhan (5th) and Other pharmaceuticals are small-sized ones for domestic consumption.

<Table 3> Top 5 of domestic pharmaceutical Company Sales

Unit : million won , %

Rank	Pharmaceutical Company Name	Sales	Share Rate	Accumulated Share Rate
1	Dong A	719,973	5.2	5.2
2	Hanmi	579,630	4.2	9.4
3	Daewoon	567,061	4.1	13.6
4	Handok	509,250	3.7	17.3
5	Yuhan	453,860	3.3	20.6

Source : KFDA(2011b)

2. Global Pharmaceutical Market

According to Intercontinental Marketing Services (IMS) Health, The global pharmaceutical market in 2010 is grew by 4.1 percent and reached a level of \$874.6 billion USD, In 2009 the pharmaceutical market has grown meager to 3.5 percent with market size of \$808 billion USD. And global drug sales will rise in 2011, Global pharmaceutical sales are nonetheless expected to grow 5 %- 7 percent in 2011, compared with 4.1percent growth in 2010. IMS expects the global pharmaceutical market to reach \$880 billion USD in 2011, up from \$875 billion USD in 2010.

A great majority of the expansion is driven by explosive growth in China, now the world's third largest market for pharmaceutical sales. Drug sales in that emerging market areexpected to grow 25%-27% in 2011, to more than \$50 billion USD.

For example, Rise of Emerging Markets including China '2003(9th Rank) → '2008(5thRank) → '2013(Expecting 3rd Rank) and Emerging Markets including China, Brazil, Turkey, Korea account for 51% of Total Market in 2009.(see to table 4 and table 5)

<Table 4> Top 15 countries of global pharmaceutical market Sales

Rank	2003	2008	2013 E
1	USA	USA	USA
2	Japan	Japan	Japan
3	Germany	France	China
4	France	Germany	Germany
5	Italy	China	France
6	U.K	Italy	Spain
7	Spain	U.K	Italy
8	Canada	Spain	Brazil
9	China	Canada	Canada
10	Brazil	Brazil	U.K
11	Mexico	Mexico	Venezuela
12	Australia	Turkey	Turkey
13	India	India	India
14	Poland	Korea	Mexico
15	Korea/17th	Australia	Korea

Source : KFDA(2011b)

<Table 5> Global pharmaceutical market trades

Unit: thousand US dollar

Classification	2008		2009		2010	
	Export	Import	Export	Import	Export	Import
Japan	216,637	451,817	238,743	480,587	304,572	706,563
China	67,503	329,900	83,170	347,215	131,835	456,788
USA	86,269	466,946	152,458	520,222	79,355	501,172
Germany	54,519	550,722	53,548	467,360	54,508	517,454
Italy	29,717	345,015	29,760	299,489	40,105	323,736
UK	41,915	245,830	18,312	279,754	34,002	311,572

Source : KFDA(2011a).

3. The problems and improvement of Pharmaceutical distribution

If measure to the problem of the Korean pharmaceutical distribution and it can divide the internal and external problems. It can be summarized as follows.

4. The internal problems

First, The disorderly problem of the wholesale distribution. Thereby, because of the wholesale distribution' small structure, the factor of lower margin of wholesale business and the lower efficiency of distribution is deteriorated. Moreover, the problems of SME company' margin is happening. In other words, Neither the local pharmaceuticals and foreign pharmaceuticals' distribution margin was reduced.

So that, the wholesale distribution of SME were under much bad situation in many hospitals branch too at soon. Meanwhile, Complicated distribution structure is culprit for impeding transparent and fair trade in domestic Market.Korean pharmaceutical distribution system with 'produce-wholesale- retail' 2-3 step wholesalers was

showed complicated and diversity aspect.

Second, The excessive promotion competition of pharmaceuticals. Specially, because of the more weak than foreign pharmaceuticals products, the R&D costs was reduced and new drug innovations was stopped. Not only use many rebate, but also sell expensive price to consumers.

Third, Complicated distribution structure. Weakening position and lowering profession. Moreover, the distrust problem of wholesale distribution was aggravated. In other words, direct selling was high level in pharmaceuticals market. Because of the large-scale wholesales with Professional marketing organizations and logistic functions are not much in Korea. Wholesale trade is not much inconvenient in hospitals and pharmaceutical companies.

5. The external problems

First, The government's repress policy of the drugs. Reluctantly have to accept this fact. In other words, because of Consistentgovernment policy of the cutting drug price, the pharmaceutical wholesalers profit is expected to reduce.

Second. the effectuation of the free trade agreement. The public of drug policy was worsened and the global pharmaceutical company profit will be more guaranteed.

this provision indicates that any pharmaceutical company which makes generics cannot have the permission of marketing its generics without approval of patent owner. Under this system, Korean firms to produce generic drugs to the foreign companies that hold the relevant patents. Foreign companies could then file patent infringement lawsuits. This would mean that pharmaceutical companies intending to produce the generics must receive confirmation from the patent holder that the patent has expired, or win a legal case. (Korea Health News, 2012)

<Table 6> The problem of the Korean pharmaceutical distribution

The internal problems	The external problems
the disorderly problem of the wholesale distribution. the excessive promotion competition of pharmaceuticals Complicated distribution structure	the government's repress policy of the drugs the effectuation of the free trade agreement

IV. The improvement of Pharmaceutical distribution

1. The internal of improvement

First, The roles and functions of the wholesale distribution have to strengthen.

The market share rate of wholesalers will be increased and its own competitiveness will be strengthened with mergers and acquisitions etc.

Second, The distribution is transparent. The distribution information is the best efficiency month for raising the transparent. Companies actively open the information and the government will implement

RFID until 2015 year for collecting the data and managing systematic.

Third, Pharmaceutical companies, wholesalers, hospitals, pharmacies etc for the spontaneous participation are required. Though the government had Unified distribution but it was disposed by the opposite extreme, that is an example of the lack of cooperation.

Fourth, It is necessary to secure the distribution centers.

2. The external environment of improvement

First, Pharmaceutical companies, wholesalers, hospitals, pharmacies etc for the spontaneous participation are required.

Second, Leading to advanced company is required. In other words, the strengthen drug store chain market is required, for example, Japanese companies continue develop diversify profits of health function food for international home shopping like Large-sized company.

V. Conclusion

This study in order to solve several practical problems in Korea pharmacies distribution market, it was listed what is happening in the practice field.

Korea pharmacies distribution companies of the excessive promotion competition is serious, Because of the disorderly problem of wholesale distribution` small structure.

Moreover, the rebate problem was appeared in order to increase the sales profit.

So the government is strengthening the dual punishment system.

Now, the effectuation of the Korea and US free trade agreement. The public of drug policy was worsened and the global pharmaceutical company profit will be more guaranteed.

So this study can be summarized as follows again. If measure to the problem of the Korean pharmaceutical distribution and it can divide the internal and external problems. The internal problems include the disorderly problem of the wholesale distribution, the excessive promotion competition of pharmaceuticals and Complicated distribution structure. The external problems include the government's repress policy of the drugs and the effectuation of the free trade agreement.

The improvement of Korea pharmaceutical distribution can divide the internal and external items.

First, Internal item of the improvement includes strengthening the roles and functions of the wholesale distribution, the distribution is transparent, pharmaceutical companies, wholesalers, hospitals, pharmacies. etc for the spontaneous participation are required, it is necessary to secure the distribution centers.

Second, The external environment of improvement includes pharmaceutical companies, wholesalers, hospitals, pharmacies etc for the spontaneous participation are required and leading to advanced company is required.

Finally, There is a clearly limitation in this paper. The lack of objective information and the scientific analysis are biggest vulnerabilities

through interviews with company representatives. However, there is implication for researchers opening new direction.

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