WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharma Profile

South Korea, 2018

Gesundheit Österreich GmbH

PPRI Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Profile South Korea

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PPRI Representatives
National Health Insurance Service: Namsun Choi, Gira Gong

Authors
College of Pharmacy, Gachon University: Sunmee Jang, Ji-hye Byun, Inmyung Song, Hyemin Cho

Editors
PPRI Secretariat, Gesundheit Österreich GmbH (Austrian Public Health Institute)

Reviewed by
Manuel Alexander Haasis, PPRI Secretariat

ÖBIG
Österreichisches Bundesinstitut für Gesundheitswesen

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MINISTERIUM FRAUEN GESUNDHEIT

Introduction

PPRI Pharma Profiles: national reporting systems on pharmaceutical pricing and reimbursement

The need for accurate and up-to-date country information has been broadly acknowledged. Information about specific issues of a country is of key importance for decision makers and researchers, even if their needs with regard to the level of detail may vary.

Within the framework of the PPRI (Pharmaceutical Pricing and Reimbursement Information) research project (2005 – beginning of 2008), the project consortium, consisting of the Austrian Public Health Institute (Gesundheit Österreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen) and the World Health Organization (WHO) developed the so-called "PPRI Pharma Profiles" as a tool for understanding, collecting and analysing pharmaceutical pricing and reimbursement information. A key principle of the PPRI Pharma Profiles was that the Profiles were written by national country experts, usually staff of competent authorities for pharmaceutical pricing and reimbursement (Ministries of Health, Medicines Agencies, Social Health Insurance institutions) represented in the PPRI network and that they were critically reviewed by project consortium members.

PPRI Pharma Profiles, which primarily focused on the out-patient pharmaceutical sector, for 23 countries were published within the years 2007 to 2009. Even if the PPRI project officially ended at the beginning of the year 2008, the PPRI network members continued contributing by updating the PPRI Pharma Profiles.

As a further development, information on the in-patient sector was integrated: The PHIS (Pharmaceutical Health Information System) project surveyed, for the first time, information about the in-patient pharmaceutical sector. The PHIS project consortium, including the Austrian Public Health Institute, the International Healthcare and Health Insurance Institute (IHHII) in Bulgaria and the Slovak Medicines Agency (SUKL), developed the PHIS Hospital Pharma report about medicines management in the hospital sector and the PHIS Pharma Profile as a comprehensive report about the pharmaceutical out-patient and in-patient sectors. The principle of involving national experts as authors remained the same. 19 PHIS Hospital Pharma reports and 5 PHIS Pharma Profiles were published. All published country reports and profiles are publicly accessible at the website of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at https://ppri.goeg.at/ppri_country_information.

Additionally, in order to allow information at a glance, posters about pharmaceutical systems and policies were produced. They are also available at the WHO Collaborating Centre's website at https://ppri.goeg.at/ppri_posters.

In order to support the production of the PPRI and PHIS Pharma Profiles, templates were matched and were made available to the authors. In the course of the years, the templates for the comprehensive profiles (in 2015 the "PPRI/PHIS Pharma Profiles were renamed again to "PPRI Pharma Profiles") were revised, further developed and updated.

The PPRI Pharma Profile 2018 is designed to comprise up-to-date information as of 2018 (or latest available year) about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

Templates and glossaries

All PPRI Pharma Profiles are based on a template which provides a homogenous outline for reporting. The templates were developed in the PPRI and PHIS projects, were circulated for review and feed-back to the PPRI/PHIS network members, were tested by the authors of the profiles and afterwards revised by consortium members, taking into account the experiences made.

Editorial guidelines provide advice to authors and reviewers and aim to increase the readability of the profiles. Readers can expect a universal approach with regard to citations, data presentations, spelling etc. across the PPRI Pharma Profiles.

To achieve clarity for authors, reviewers and readers and thus to create a common understanding of the concepts and terms used, a glossary was developed in the early times of the PPRI project. It has been regularly updated since. The most updated version of the Glossary of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies can be found at the WHO Collaborating Centre's website at https://ppri.goeg.at/ppri-glossary. Authors of the PPRI Pharma Profiles are requested to adhere to the Glossary.

PPRI, PHIS, and WHO Collaborating Centre

Pharmaceutical Pricing and Reimbursement Information (PPRI) was originally a research project, co-funded by the European Commission, Directorate-General Public Health and Consumers. It was performed from 2005 till early 2008. In the course of the project the PPRI network was established, and a set of pharmaceutical indicators, filled with real data from 27 PPRI countries, as well as more than 20 country reports (PPRI Pharma Profiles) and brief overviews on the pharmaceutical systems (country information) were produced.

Today, Pharmaceutical Pricing and Reimbursement Information (PPRI) is a networking and information-sharing initiative on burning issues of pharmaceutical policies from a public health perspective. The PPRI network involves representatives from around 80 institutions: These are public authorities and third party payers from 47 countries (mainly European countries, including all 28 EU Member States) as well as European and international institutions such as European Commission services and agencies, OECD, WHO (HQ and Regional Office for Europe) and World Bank.

In the on-going PPRI initiative, the networking of the public authorities continues via regular networking meetings and continuous sharing of relevant information for decision-making, including updates of country-specific information. The PPRI secretariat is hosted at the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (see below).

The PPRI project was selected by the Executive Agency for Health and Consumers, in collaboration with the Health Programme's National Focal Points (NFP) and the Directorate General

for Health and Consumers (DG SANCO), as a good practice example of EU Public Health projects with an important impact for EU Member States (https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/EAHC_NFP_EUHealthProgramme_ImpactProjects_4.pdf).

Pharmaceutical Health Information System (PHIS) was a European Commission co-funded project which ran from September 2008 to April 2011. The project aimed to increase knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the EU Member States, covering both the out-patient and the in-patient sectors. A special focus of the project was on Hospital Pharma, with a European survey of medicines management in hospitals in the EU Member States and an investigation and analysis of official and actual prices of medicines in hospitals in selected case study countries. Methodology tools, in particular with regard to terminology, indicators and reporting tools, were further developed based on work started in PPRI.

The Pharmacoeconomics Department (former Health Economics Department) of the Austrian Public Health Institute (GÖG) was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and redesignated in 2014 and in 2018. The Centre continues methodology work started under the framework of the PPRI and PHIS projects: One of the Centre's explicit tasks is to develop the tool for describing and analysing national pharmaceutical pricing and reimbursement systems ("Pharma Profiles"). WHO Collaborating Centre staff are also involved as experts in the development of the WHO Pharmaceutical Country Profiles by supporting to expand the current tool of the "PPRI Pharma Profiles" for the European countries, and adapting it so that it can describe the pharmaceutical sector in other health system arrangements.

Within the PPRI and PHIS projects, websites were established. Policy makers, researchers and the interested public are thus offered open access to our findings and methodological tools developed. The PPRI and PHIS project websites are no longer maintained, all relevant PPRI and PHIS information was integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: https://ppri.goeg.at. The website of the Centre is designed to serve as an information platform about pharmaceutical policies, and it includes published profiles, indicators of the PHIS database, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

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ATC	Anatomic therapeutic chemical classification
DBCAC	Drug Benefit Coverage Assessment Committee
DRG	Diagnosis Related Group
DUR	Drug Utilization Review system
INN	International Non-proprietary Name
GDP	Gross Domestic Product
HTA	Health Technology Assessment
HE	Health Expenditure
HIPC	Health Insurance Policy Council
HIRA	Health Insurance Review and Assessment Service
KCDC	Korea Centers for Disease Control and Prevention
MFDS	Ministry of Food and Drug Safety
MOHW	Ministry of Health and Welfare
NCU	National Currency Unit
NHI	National Health Insurance
NHIS	National Health Insurance Service
NHS	National Health Service
NMEs	New Molecular Entities
OECD	Organisation for Economic Co-operation and Development
OPP	Out-Of-Pocket payment
OTC	Over-The-Counter medicine
PHIS	Pharmaceutical Health Information System
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicine

PPP	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information Project
PRP	Pharmacy Retail Price
QALY	Quality Adjusted Life Year
SHI	Social Health Insurance
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WHO	World Health Organisation

1 Health care system

This section provides a brief introduction to the demographic and economic situation of South Korea, as well as the accessibility of the health care system.

1.1 Population and age structure

South Korea's total population stands at 51.0 million as of 2015. The land area is 100,295 km^2, with an average population density of 511.6 people per 1 km^2. Over 50% of the population is concentrated in the metropolitan areas of Seoul, Gyeonggi, and Incheon.[1]

The national health status in South Korea has dramatically improved mainly because of rapid economic growth and high accessibility to health services resulting in universal health coverage. In 2014, the average life expectancy was 85.5 years for women, ranking the third-highest in the world, and 78.8 years for men, ranking 18th worldwide. Infant mortality is 3.0 per 1,000 infants. It is lower than the OECD average of 4 per 1,000 infants.[2]

South Korea is the most rapidly aging country in the world. South Korea became an aging society in which the number of people aged 65 or older was over 7% in 2000, and it is expected to become a super-aged society in which the elderly aged 65 or older is estimated to be over 21% of the total population in 2026. While the elderly population is increasing, the number of people aged 14 or younger continues to decrease. The average number of lifetime births per woman is 1.25 in 2014, which is much lower than the OECD average fertility rate of 1.68.[3]

The leading causes of mortality in 2015 are cancer (150.8 per 100,000 population), heart disease (55.6 per 100,000 population), cerebrovascular disease (48.0 per 100,000 population), pneumonia (28.9 per 100,000 population), and suicide (26.5 per 100,000 population).[4]

[1] Ministry of Land, Infrastructure and Transport, Land statistical book, 2016

[2] World Health Organization, World Health Statistics, 2016

[3] United Nations, Department of Economic and Social Affairs, Population Division, 2015; World Population Ageing, 2015

[4] Statistics Korea, Cause of death statistics, 2015

Table 1.1: South Korea - Demographic indicators

Demography	2000	2005	2010	2015
▪ Total population[1)*] (thousand)	47,008	48,185	49,554	51,015
Population aged 0-14	9,911	9,223	7,979	7,030
Population aged 15-64	33,702	34,641	36,209	37,444
Population aged > 64	3,395	4,321	5,366	6,541
▪ Life expectancy at birth[2)](year)	76.0	78.2	80.2	82.1
▪ Life expectancy at age 65	81.4	82.7	84.1	85.3

*Mid-year population as of July 1st.

Source: 1) Statistics Korea, Results of median projection from Future Population Projection: 2015-2065, 2016

2) Statistics Korea, Life expectancy figures were obtained from the abridged life table (at 5-year age intervals), 2016

1.2 Organisation of the health care system

Health insurance was introduced as a part of social insurance in South Korea in 1977. After only 12 years, Korea achieved universal health coverage in 1989. Currently, the National Health Insurance (NHI) covers 97% of the population, while the remaining 3% are covered by the Medical Aid program. Furthermore, South Korea implemented Long Term Care Insurance (LTCI) in 2008 to provide care services to elderly who have difficulties in performing daily activities.

All residents in South Korea are eligible for NHI. Overseas Koreans and foreigners residing in South Korea can also join the NHI program by registering with the NHI. The NHI and Medical Aid program covers inpatient, outpatient, emergency services, dental services and pharmacy services. Benefits in cash cover 80% of the standard price for support equipment (e.g. canes, wheelchairs and hearing aids) for people who are registered as disabled.[5]

The majority of health care services are provided by private health care institutions[6], while public health care institutions provide a small range of services. All medical institutions and pharmacies are obliged to provide services covered by NHI.

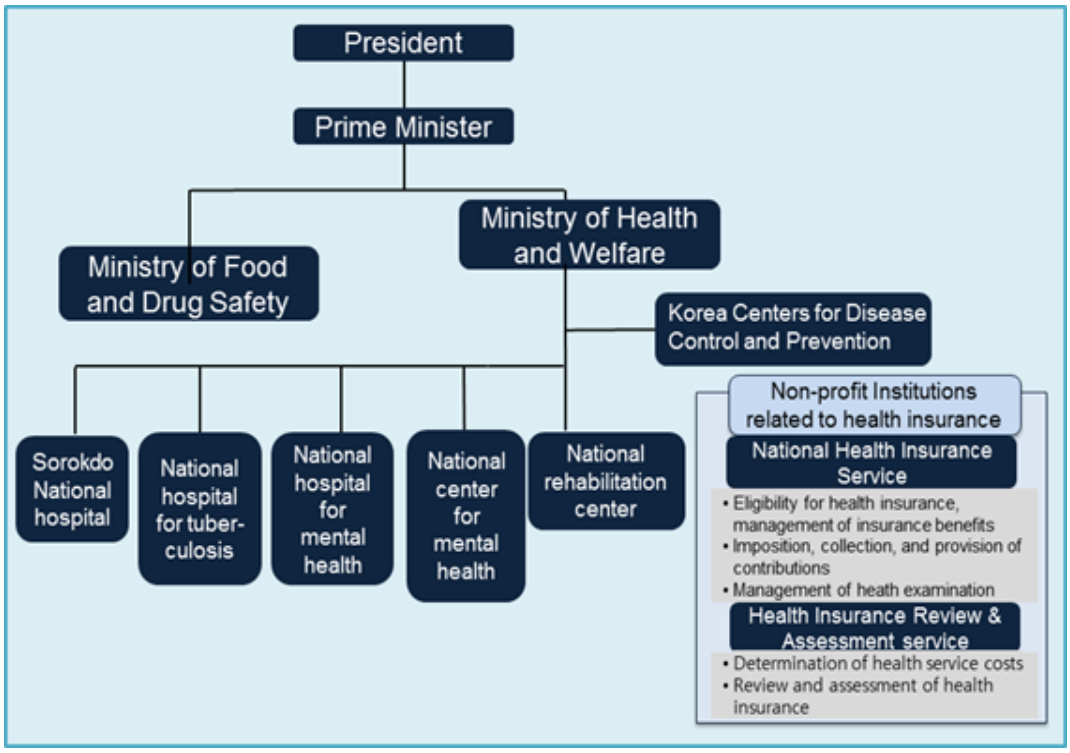
The central government organizations supporting the health care system in South Korea include the Ministry of Health and Welfare (MOHW), the Ministry of Food and Drug Safety (MFDS), and the Korea Centers for Disease Control and Prevention (KCDC). The MOHW bears responsibility for the planning and development of national health and welfare policies, and has control over national hospitals. The MFDS is responsible for the approval of foods, medicines, and medical devices. The main role of the KCDC is the surveillance of infectious diseases, including infectious diseases abroad, which can cause a national crisis if they are imported into Korea (Fig. 1.1).

Local government organizations include departments of cities and provinces (administrative levels of *si* and *do*), and the public health centers of districts (administrative levels of *si*, *gun*, and *gu*) that carry out various health care initiatives.

[5] NHIS, National health insurance system of Korea, 2015

[6] Hospital, dental clinics, traditional Korean medical hospitals, clinics, and health centers, pharmacies are all included.

Figure 1.1: South Korea - Central governmental organizations involved in health care



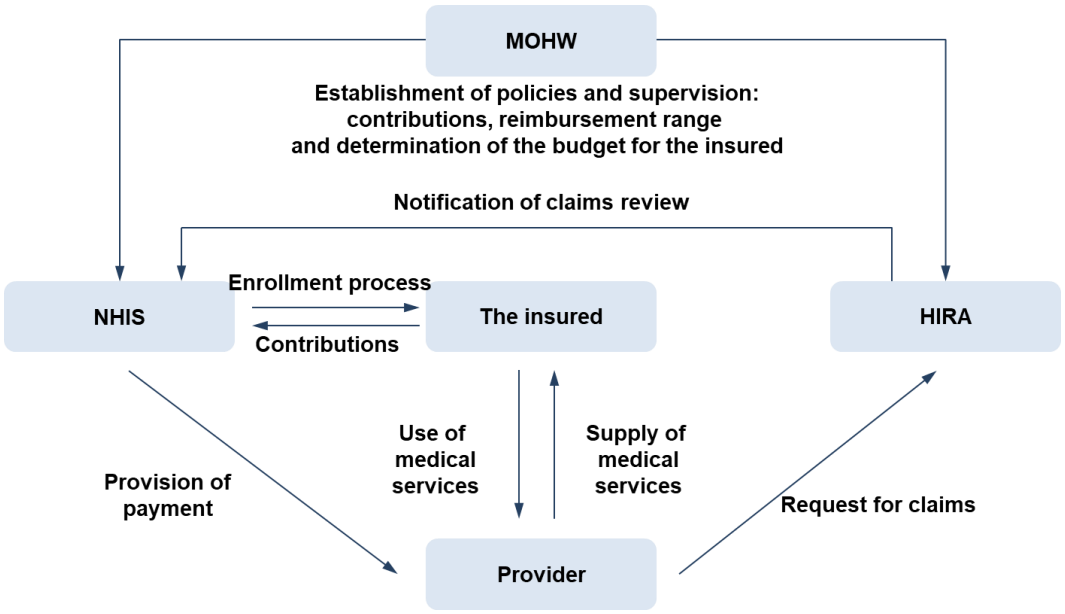
Since the NHI requires extensive management, the National Health Insurance Service (NHIS) and the Health Insurance Review & Assessment Service (HIRA) have been established as government institutions working alongside the MOHW to carry out major operative tasks. Figure 1.2 presents a summary of how the NHI operates.

The MOHW directs and supervises policy measures related to the NHI and determines contributions and insurance benefits. As a single payer, the NHIS manages the eligibility of NHI beneficiaries and their dependents, and imposes and collects contributions. It also provides insurance payments to medical institutions and pharmacies after a review. In addition, the NHIS negotiates fee schedule with representatives of health care providers once a year and conducts negotiations to set the prices of new medicines with pharmaceutical companies.

The HIRA is responsible for reviewing the fee claims and assessing the quality of medical and pharmaceutical services. Approximately 95% of the claims of medical institutions and pharmacies are requested electronically and the determined costs are provided by the NHIS after reviewing by the HIRA. Reimbursement is generally based on fee-for-service (FFS), except for some services, which are paid by the diagnosis-related group (DRG).[7]

[7] Services that are paid by DRGs in 2017 include cataract, tonsil and adenoid surgery, anal surgery, hernia surgery, appendectomy, hysterectomy (excluding neoplasm), and caesarean section.

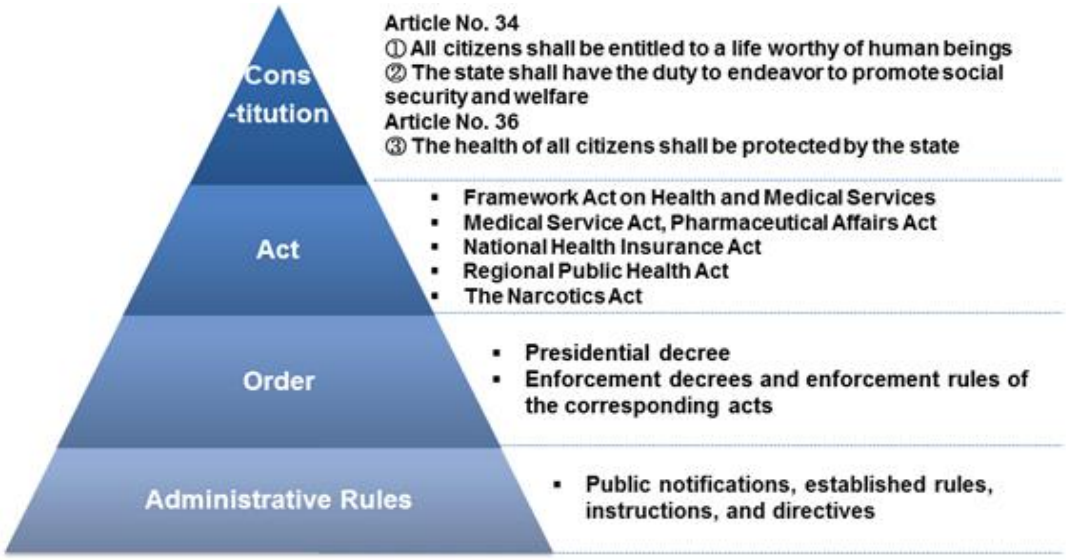
Figure 1.2: South Korea-Operation of the National Health Insurance system



Source: Korean Association of Pharmacy Education, Social pharmacy subcommittee, Administrative and Managerial Pharmacy, Panmun Education, 2013
Ministry of Health and Welfare, National Health Insurance System, 2017

The legal grounds underlying South Korea's health care system are presented in Figure 1.3. On the basis of Articles 34 and 36 of the Constitution, the Framework Act on Health and Medical Service, the National Health Insurance Act, the Medical Service Act, and the Pharmaceutical Affairs Act were established, and relevant ordinances and administrative rules have been enacted and are enforced based on these Acts.

Figure 1.3: South Korea - Legal basis of health care



1.3 Health expenditure

Health expenditures have been increasing steadily since 2000 (Table 1.2). The ratio of health expenditures to gross domestic product (GDP) was only 4.0% in 2000, but increased to 7.1% in 2014. Health expenditures are expected to increase due to the rapidly aging population. The proportion of public resources allocated to current health expenditures is 56.5% in 2014, which is lower than the OECD average of 73.1%.

Table 1.2: South Korea - Health expenditure

Health expenditure	2000	2005	2010	2014
▪ GDP (trillion KRW)	635.2	919.8	1,265.3	1,486.1
▪ Health expenditures as a percent of GDP (%)	4.0	5.0	6.4	7.1
▪ Current health expenditures (billion KRW)	25,434	46,335	81,044	105,014
- thereof public (%)	54.0	57.1	59.1	56.5
- thereof private (%)	46.0	42.9	40.9	43.5
▪ HE in the out-patient sector* (billion KRW)	8,931	16,907	26,241	35,692
- thereof public (%)	n.a.	n.a.	n.a.	n.a.
- thereof private (%)	n.a.	n.a.	n.a.	n.a.
▪ HE in the in-patient sector[1)] (billion KRW)	7,724	13,180	26,007	34,814
- thereof public	n.a.	n.a.	n.a.	n.a.
- thereof private	n.a.	n.a.	n.a.	n.a.

Health expenditure	2000	2005	2010	2014
▪ Other[2] (billion KRW)	8,779	16,248	28,796	34,508
▪ Exchange rate[3] (KRW per $)	1,131.12	1,024.13	1,156.00	1,053.12

GDP = gross domestic product, HE = health expenditure, NCU = national currency unit, n.a. = not available

Source: Jeong et al. Korean National Health Accounts in 2014, MOHW, 2016.

Note: * National health expenditures were measured as current health expenditures.

1) Inpatient prescriptions and auxiliary medical services (clinical pathology examinations, diagnostic imaging, ambulance and first aid, etc.) are health expenditures included in the inpatient sector.

2) Other sectors refer to the rest of current health expenditures not including inpatient and outpatient costs; this category includes the costs of medical goods such as medicines, in-home services, same-day services, long-term day-care services, auxiliary medical services, preventive care services, and governance.

3) The Bank of Korea annual average exchange rate was applied.

1.4 Sources of funding

In 2014, public sources such as government subsidies and contributions accounted for 56.5% of national healthcare funding, while private sources comprising private health insurance and out-of-pocket payments by households accounted for 43.5%. Additionally, approximately 81.9% of the sum corresponding to the government and mandatory health insurance was accounted for by health insurance, which depended on contributions for over 80% of its financial resources. A total of 38.7 trillion KRW, corresponding to 84.7% of all private sources, was contributed by households, showing that the health expenditures of households were high (Fig. 1.4).

Figure 1.4: South Korea - Composition of funding for current health expenditures

Category	Size(KRW)	Proportion
Government and mandatory health insurance	59.3 trillion	56.5%
- Government	10.8 trillion	10.2%
- Mandatory health insurance	48.6 trillion	46.3%
Private resources	45.7 trillion	43.5%
- Optional entry system	7.0 trillion	6.7%
Private health insurance	6.2 trillion	5.9%
Nonprofit organizations	0.6 trillion	0.6%
Companies	0.1 trillion	0.1%
- Household burden	38.7 trillion	36.8%
Total current health expenditures	105.0 trillion	100%

Source: Jeong et al. Korean National Health Accounts in 2014, MOHW, 2016.

2 Pharmaceutical system

This section aims to explain the pharmaceutical system in Korea, with a focus on the pharmaceutical organizations, legal framework, and their major responsibilities for Korean pharmaceutical products.

2.1 Organisation of the pharmaceutical system

In South Korea, medicines have to be approved by the MFDS before medicines are made available on the market. To obtain approval from the MFDS, pharmaceutical companies must submit the safety and efficacy data and Good Manufacturing Practice (GMP) data of the medicine. New medicines that need safety and efficacy review are examined by the MFDS, while generics are reviewed by regional offices of the MFDS because generics do not require an additional safety and efficacy review. Expedited review is applied to medicines that need prompt approval to treat serious, life-threatening diseases, such as AIDS and cancer.

A positive list system is implemented in Korea, which grants benefits selectively to products with excellent treatment and high economic value. To list a medicine on the positive list, the pharmaceutical company should prepare and submit a dossier to prove if a new medicine is cost-effective compared to a pre-existing medicine. Nonetheless, essential medicines that are used for serious, life-threatening diseases without an alternative treatment method can be listed in the national drug formulary list, even if their cost-effectiveness has not been proven.

The HIRA is responsible for assessing the appropriateness of benefit inclusion. The HIRA convenes a Drug Benefit Coverage Assessment Committee (DBCAC) comprised of representatives of consumer and health professional groups and related experts to assess whether a new medicine will be listed in the national drug formulary list. Subsequently, a process of setting the price of the new medicine starts. New medicines will be subject to go through price negotiation with the NHIS. The price of generic medicines, however, is determined by a formula. Once the MOHW sets the price of a medicine after a review by the Health Insurance Policy Council (HIPC) and publishes the price, the medicine will be reimbursable. Medicines approved by MFDS that are not listed in the health insurance system have to be paid entirely out of pocket. Table 2.1 summarizes the laws and organizations governing approval, listing, and reimbursement of Medicines in South Korea.

Figure 2.1: South Korea - System for the approval, listing, and reimbursement

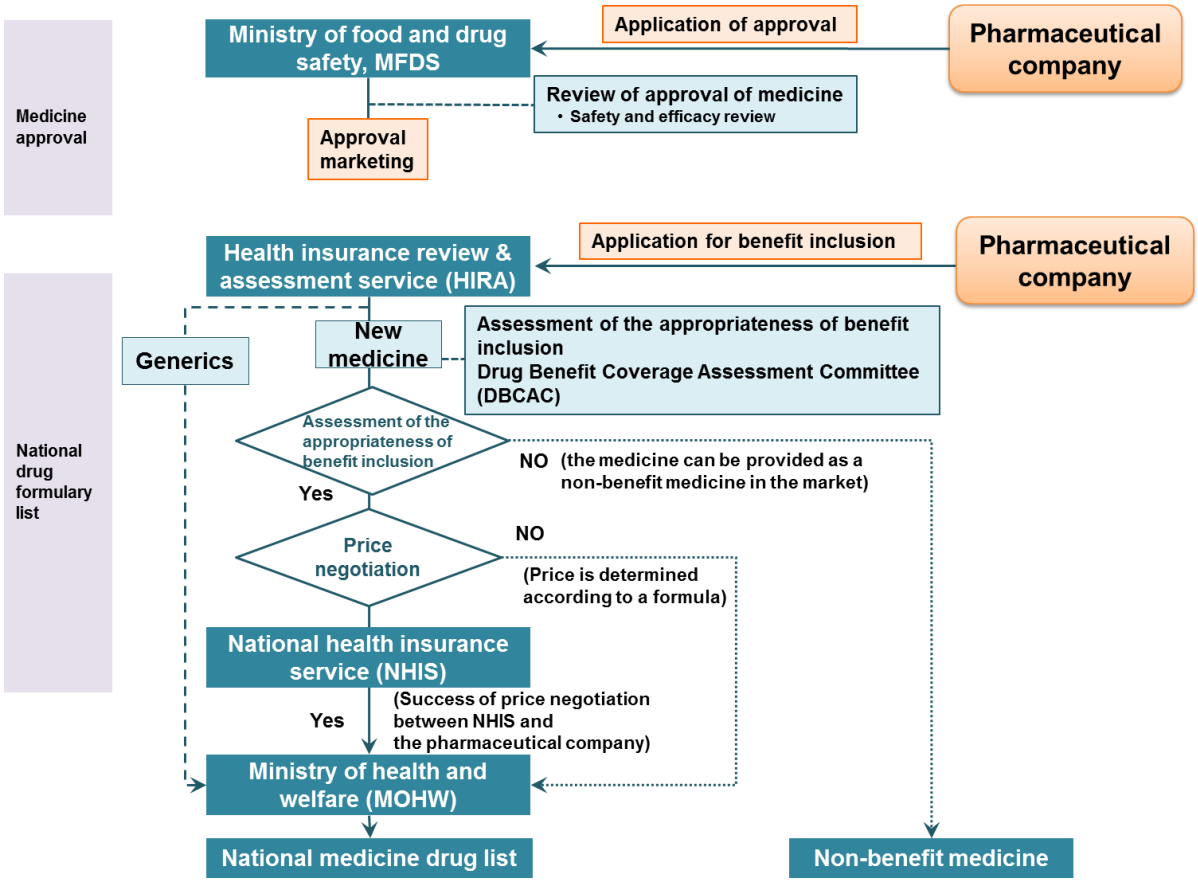


Table 2.1: South Korea - Legal basis and actors (authorities and market players) of the pharmaceutical system, 2017

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Market authorisation	• Pharmaceutical Affairs Act	• All registered/licensed pharmaceuticals (POM and OTC) used regardless of the inpatient or outpatient sector	• Ministry of Food and Drug Safety, MFDS	• Approval, classification and vigilance of all medicines and medical devices used in Korea	• Korea Pharmaceutical and Bio-Pharma Manufacturers Association, KPBMA • Korean Research-based Pharmaceutical Industry Association, KRPIA
Pricing / Purchasing	• National Health Insurance Act	• All reimbursed POM prescribed in the inpatient or outpatient sector	• Ministry of Health and Welfare, MOHW • National Health Insurance Service, NHIS • Health Insurance Review and Assessment Service, HIRA	• Decision-making or negotiation on pharmaceutical pricing and reimbursement • Price volume Control management	• Korea Pharmaceutical and Bio-Pharma Manufacturers Association, KPBMA • Korea Research-based Pharmaceutical Industry Association, KRPIA
Reimbursement	• National Health Insurance Act	• All reimbursed POM prescribed in the inpatient or outpatient sector	• National Health Insurance Service, NHIS • Health Insurance Review and Assessment Service, HIRA	• HIRA – review of medical claims • NHIS – in charge of reimbursing	• Health care institutions (general hospitals, hospitals, clinics, dental hospitals/clinics. Traditional Korean medicine hospitals/clinics, public health centers, pharmacies)
Promotion	• Pharmaceutical Affairs Act	• OTC or quasi- medicines used in the inpatient or outpatient sector	• Ministry of Food and Drug Safety, MFDS	• Monitoring informational/ and promotional activities of advertisement	• Korea Pharmaceutical and Bio-Pharma Manufacturers Association, KPBMA • Korean Research-based Pharmaceutical Industry Association, KRPIA

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Distribution	• Pharmaceutical Affairs Act • National Health Insurance Act • Medical Service Act • Fair trade agreement	• All registered/licensed pharmaceuticals (POM, OTC) used in the inpatient or outpatient sector	• Ministry of Health and Welfare, MOHW • Ministry of Food and Drug Safety, MFDS • Health Insurance Review and Assessment Service, HIRA	• Supervising manufacturers, importers, wholesalers, hospitals and pharmacies, production and sales performance	• Korea Pharmaceutical Distribution Association, KPDA • Korea Pharmaceutical and Bio-Pharma Manufacturers Association, KPBMA • Korean Research-based Pharmaceutical Industry Association, KRPIA
Pharmaco-Vigilance	• Pharmaceutical Affairs Act	• Pharmaceutical manufacturers/ importers/ retailers	• Ministry of Food and Drug Safety, MFDS • Korea Institute of Drug Safety and Risk Management	• Pharmacovigilance • Medicine revaluation • Self-reporting of adverse events	• Korea Pharmaceutical and Bio-Pharma Manufacturers Association, KPBMA • Korean Research-based Pharmaceutical Industry Association, KRPIA • Korean Pharmaceutical Association, KPA • Korean Medical Association, KMA • Korea Institute of Drug Safety and Risk Management

2.2 Availability of and access to medicines

In South Korea, universal health coverage includes all medicines in the benefits package, so that NHI beneficiaries can use medicines at a reasonable cost. NHI was firstly started in 1989, and until 2006, most of the approved medicines were covered by the NHI. After the positive list system was introduced in 2007, the number of listed medicines decreased, however, around 20,000 medicines are still covered by the NHI.

Regarding the financial burden for patients, out-of-pocket payments for prescription medicines are made via coinsurance, with around 30% of pharmaceutical expenditure. In order to improve the accessibility of medicines for vulnerable people, various mitigation measures have been implemented. If a medicine price is below the price (10,000 KRW), the elderly pay only 10% of total price out of pocket. Children under 6 years of age, cancer patients, and patients with rare and incurable diseases pay only 5%-10% of the pharmaceutical expenditure out of pocket. In addition, the NHIS implements the Co-payment Ceiling System in which an annual cap on cost-sharing is applicable.

In South Korea, there were 41 pharmacies per 100,000 people in 2015, more than the OECD average of 25.1 per 100,000 people. Therefore, patients who receive outpatient prescriptions from health care institutions can visit the pharmacy and receive dispensing services relatively easily.[8] Statistics show that in 2015, the number of prescriptions dispensed in pharmacies reached about 500 million[9], and the total number of prescription-days reached 6.19 billion. The total cost covered by the health insurance for pharmacies, amounted to 13.9 trillion KRW in 2015, corresponding to approximately 24.0% of the total expenditure covered by NHI (57.9 trillion KRW).[10]

Table 2.2: South Korea - Annual prescriptions in the out-patient sector

Prescriptions		2005	2010	2015
Prescriptions in volume	No. of prescriptions	399,521,048	465,278,855	484,662,554
	Prescription-days	3,139,059,143	4,821,444,633	6,189,853,113
Prescriptions in value	Prescription fee, drug cost (1,000 KRW)	7,022,889,526	11,485,531,777	13,095,006,590

Source: National Health Insurance Statistical Yearbook, NHIS

[8] OECD, Health at a Glance, 2015

[9] This corresponds to 6.19 billion prescribing/dispensing days.

[10] NHIS, Health Insurance Statistics, 2015

It takes approximately 120 days for a pharmaceutical company to receive medicine approval from the MFDS. However, the actual time required for approval may vary as the MFDS may request supplementary data to confirm the safety and efficacy of medicines. Innovative medicines, on the other hand, are subject to expedited review.

Medicines for expedited review include the followings: medicines to treat life-threatening diseases such as AIDS and cancers; medicines that need urgent introduction because it is impossible to treat the relevant diseases with existing therapies; orphan medicines, and DNA chips. Table 2.3 shows the annual number of new medicine approvals. Between 2005 and 2010, the number of newly approved medicines was 436 (252 when classified by ingredient names). In contrast, between 2010 and 2015, the number of newly approved medicines decreased to 203 (123 when classified by ingredient names).

*Table 2.3: South Korea - Number of medicines * and new molecular entities*

New molecular entities	2005 - 2010	2010 - 2015
Number of new medicines approvals[1) **]	436	203
Number of new molecular entities [2),3) ***]	252	123

Source: 1) MFDS, Status of New Drug Approval by Year: 2003-2015
2) MFDS, 2015 drug approval report, 2016
3) MFDS, 2010 drug approval report, 2011

Note: * New medicines: Medicine designated by the Director of the MFDS (Article 2, Paragraph 8 of the Pharmaceutical Affairs Law) as a new material medicine with a novel chemical composition or a complex medication with new material as an active ingredient.

** The same compound in different dose or formulation will be approved as a different product and therefore the number of new molecules may be different from the number of new medicines approvals.

*** The number of new molecular entities was calculated based on the number of new substances, without taking into account differences in content, formulation, or active groups.

When a pharmaceutical company submits an application for listing, medicines are subject to assessment of the appropriateness of benefit inclusion and price negotiations sequentially. The MOHW then decides the price and announces it to the public. The total process takes approximately 210 days. However, for antineoplastic medicines, the actual time it takes is approximately 300 days[11], due to extra time taken to submit and review supplementary data.[12] To

[11] According to a press release by the MOHW, the average time taken from submission of an application for reimbursement decision to listing for 23 new anti-cancer compounds reviewed by the DBCAC of the HIRA between 2011- 2015 was approximately 310 days. This includes on average 224 days for application by the pharmaceutical company to Hira's notification of its decision, 60 days for price negotiations with the NHIS, and 30 days. 2016.

[12] Korea Health Industry Development Institute (KHIDI), Health Industry Statistical Book, 2017

improve the availability of new medicines, the Korean government is planning to shorten the time required for listing.

2.3 Development of the pharmaceutical sales

Medicines in South Korea are classified into three categories: prescription only medicines (POMs), over-the-counter medicines (OTCs) that can be sold at pharmacies and other OTCs that can be sold at convenient stores. Currently, approximately 20 OTCs with proven safety are sold at convenient stores. The size of the pharmaceutical market amounts to 20 trillion KRW. The production of POM amounted to 12.4 trillion KRW and that of OTC totalled 2.4 trillion KRW in 2015. Although the production of bio- medicines has grown at an average annual growth rate of 7.1%, the annual export growth rate remarkably increased to 18.5%.

Table 2.4: South Korea - Pharmaceutical market

(Units: billion KRW, %)

New molecular entities	2011	2012	2013	2014	2015	CAGR (2011-2015) (%)
Medicines[1]						
Manufacture	15,597	15,714	16,376	16,419	16,970	2.1
Export	1,959	2,341	2,331	2,544	3,335	14.2
Import	5,547	5,845	5,279	5,495	5,602	0.2
Trade balance	-3,588	-3,504	-2,948	-2,951	-2,267	-
Market volume	19,185	19,218	19,324	19,371	19,237	0.1
Medicines (OTC/POM: excluding quasi-drugs and raw materials for medicine)[2]						
OTC	2,499	2,297	2,372	2,413	2,434	-0.7
POM	11,611	11,453	11,761	11,868	12,422	1.7
Total	14,109	13,750	14,133	14,281	14,856	1.3
Bio-pharmaceuticals[3]						
Manufacture	261	272	278	287	343	7.1
Export	96	114	114	134	189	18.5
Import	118	124	133	122	122	0.8
Trade balance	-22	-10	-19	12	67	-
Market volume	283	282	296	275	275	-0.7

Source: Korea Health Industry Development Institute, Health Industry Statistical Book, 2017

Note: 1) Medicines include finished products, narcotics, ultra-narcotics, and psychotropics, raw materials (Korean medicines)

2) Exclude quasi-medicines and raw materials

3) Include antibiotics, anti-cancer medicines, vaccines, hormones, immune agents, blood products, growth hormones, next generation therapeutics (gene therapeutics, cell therapeutics and cloned organs), diagnostic kits, animal medicines, other bio-medicines)

2.4 Pharmaceutical consumption

Pharmaceutical consumption in South Korea was estimated to be 1153.7 defined daily doses (DDDs) in 2008 and has steadily increased to reach 1559.2 DDDs in 2014. Population aging is expected to be accelerated and therefore the consumption of medicines will continue to increase.

Table 2.5: South Korea - Annual pharmaceutical consumption

(Unit: DDD/1,000/1day)

Consumption	2000	2008	2010	2011	2013	2014
Total pharmaceutical consumption[1]						
In packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	1153.7	1280.6	1275.9	1446.6	1559.2
Pharmaceutical consumption in the in-patient sector						
In packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the out-patient sector						
In packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = defined daily doses, n.a. = not available

Source: MOHW, Statistics on consumption of medicines and sales, 2014.

Note: 1) Medicine consumption by the ATC classification

2.5 Generics

Although there are no accurate statistical data on the market volume of generics in South Korea, the size of the generic market can be estimated based on previous research. The generic market is about 41% of the total medicine market (Table 2.6). Generic medicine sales for outpatient use amounted to 41.8% of total outpatient medicine sales. Sales of generic medicines for inpatient prescriptions accounted for 34.3% of all inpatient medicine sales, which is lower than the overall average.

Table 2.6: South Korea - Development of the generic shares in value

(Unit: %)

Generic share	Value	
	2007	2012
Shares in % of total market (inpatient/ outpatient)	41.0[1)]	40.9[2)]
Shares in % of total outpatient market	n.a.	41.8[2)]
Shares in % of outpatient reimbursement market	n.a.	n.a.
Shares in % of outpatient off-patent market	n.a.	n.a.
Shares in % of the inpatient market	n.a.	34.3[2)]

n,a = not available

Source: 1) Lee et al., Generic Utilization the Korean National Health Insurance Market; Cost, Volume and Influencing Factors, YakhakHoeji.

2) Park et al., In-depth analysis of medicine consumption and sales statistics in 2012, Korea Institute for Health and Social Affairs (KIHASA), 2013

2.6 Top 10 medicines

Table 2.7 and Table 2.8 present top 10 medicines in NHI expenditures. In the outpatient sector, the top 3 active ingredients in terms of total prescription value were atorvastatin, clopidogrel, and rosuvastatin. Cardiovascular medicines, including medicines for dyslipidemia, are also among the top 10 medicines on the list. Medications for Alzheimer disease, such as donepezil, are also commonly prescribed, ranking sixth on this list.

Table 2.7: South Korea - Top 10 active ingredients in prescription value in the out-patient sector, 2016

Rank	Top active ingredients used in the out-patient sector, ranked expenditure	
1	C10AA05	Atorvastatin
2	B01AC04	Clopidogrel
3	C10AA07	Rosuvastatin
4	N07AX02	Choline alfoscerate
5	J05AF07	Tenofovir disoproxil
6	N06DA02	Donepezil
7	A02BA	Ranitidine, sucralfate, tripotassium bismuth dicitrate
8	J01DC04	Cefaclor
9	J05AF10	Entecavir
10	G04CA02	Tamsulosin

Among the medicines that were frequently used in the inpatient sector, trastuzumab, an antineoplastic medicine, ranked first. Sodium chloride ranked second; iohexol, which is used as a contrast material, ranked third, bevacizumab, an antineoplastic agent, ranked fourth, and Human anti-hepatitis B immunoglobulin, ranked fifth. Oral medicines were most prescribed for outpatients and injectables for inpatients.

Table 2.8: South Korea - Top 10 active ingredients in value and volume in the in-patient sector, 2016

Rank	Top active ingredients used in the in-patient sector, ranked expenditure	
1	L01XC03	Trastuzumab
2	B05XA03	Sodium chloride
3	V08AB02	Iohexol
4	L01XC07	Bevacizumab
5	J06BB04	Human anti-hepatitis B immunoglobulin
6	L04AB04	Adalimumab
7	L04AD02	Tacrolimus
8	V08AB04	Iopamidol
9	J01DD04	Ceftriaxone
10	B02BD02	Recombinant blood coagulation factor VIII

Table 2.9 and Table 2.10 show the total production value of medicines based on cost classified by therapeutic category including medicines. The most produced POMs were antibiotics for gram-positive and gram-negative bacteria which were valued at 1,120 billion KRW, followed by antihypertensive and antiarteriosclerotic agents. Notably, the production of medications for the central nervous system, which ranked in seventh place, increased by 20.0% from the previous year.

Table 2.9: South Korea - Top 10 therapeutic groups in POM

(Units: million KRW; %)

Rank	Therapeutic group	Production Value		YOY growth rate
		2014	2015	
1	Antibiotics for Gram-positive and Gram-negative bacteria	1,076,104	1,121,285	4.2
2	Antihypertensive agents	1,015,511	1,053,275	3.7
3	Antiarteriosclerotic agents	910,189	951,585	4.5
4	Antipeptic ulcer agents	800,234	844,044	5.5
5	Antipyretics, analgesics and anti-inflammatory agents	552,079	615,529	11.5
6	Blood products	544,716	553,907	1.7
7	Central nervous system agents	383,454	460,027	20.0

Rank	Therapeutic group	Production Value		YOY growth rate
		2014	2015	
8	Cardiac medications	406,453	428,539	5.4
9	Unclassified metabolic medications	359,580	428,272	19.1
10	Vaccines	340,061	399,717	17.5
Total (POM)		11,867,509	12,421,785	4.7

Source: KHIDI, Health Industry Statistical Book, 2017

Note: * YoY: Year on year

In the OTC category, top five products in production value were antipyretics and analgesics (both with anti-inflammatory agents), antitussives, cardiac medications, and oral and dental medications. Polyvitamines and other vitamine supplements ranked sixth and eighth, respectively, in consumption, and showed the highest rate of growth over the previous year.

Table 2.10: South Korea-Top 10 therapeutic groups in OTC

(Units: million KRW; %)

Rank	Therapeutic group	Production Value		YOY growth rate
		2014	2015	
1	Antipyretics, analgesics, and anti-inflammatory agents	328,516	323,153	-1.6
2	Analgesics, antipruritics, astringents, and anti-inflammatory agents.	210,712	210,124	-0.3
3	Antitussives, mucolytic agents	130,742	154,208	17.9
4	Cardiac medications	161,209	144,513	-10.4
5	Oral and dental medications	129,376	127,214	-1.7
6	Polyvitamines (excluding vitamin A, polyvitamine D)	87,807	109,051	24.2
7	Stomach/digestive	98,078	105,587	7.7
8	Vitamines, others	75,816	95,589	26.1
9	Antacids	95,961	95,260	-0.7
10	Hepatitis medications	82,156	87,628	6.7
Total(OTC)		2,412,973	2,434,240	0.9

Source: KHIDI, Health Industry Statistical Book, 2017

2.7 Market players

2.7.1 Industry

The number of pharmaceutical companies was 357 in 2015, and the average production amount per company was about 41.6 billion KRW. There are a large number of small firms which account for 56.8% of all firms and their average annual production is below 10 billion KRW.

Table 2.11: South Korea - Current status of pharmaceutical companies (in terms of production scale, 2015)

Production scale (billion KRW)	Number of companies	Total production value (million KRW)	Share	Average production value (million KRW)
Total	357	14,856,025	100.0	41,614
Less than 1	125	18,311	0.1	146
1-5	50	132,116	0.9	2,642
5-10	28	208,104	1.4	7,432
10-50	77	2,033,369	13.7	26,407
50-100	36	2,494,303	16.8	69,286
100-300	31	5,309,294	35.7	171,268
300-500	5	1,820,359	12.3	364,072
Over 500	5	2,840,169	19.1	568,034

Source: KHIDI, Pharmaceutical Industry Analysis Report, 2016

2.7.2 Wholesalers

There were a total of 2014 medicine wholesalers[13] in Korea in 2014. Their total revenues amounted to 25.8 trillion KRW. In 2014, while the proportion of wholesalers with at least 100 billion KRW in revenues was only 2.6%, their total revenues accounted for 52.3% of the revenues of all wholesalers. In contrast, small wholesalers with less than 10 billion KRW in revenue accounted for 81.8% of all wholesalers, but only 15.8% of the total revenues of all wholesalers.[14]

Wholesalers were responsible for 87.3% of all medicines (in monetary terms) distributed to medical institutions and pharmacies in 2014, whereas pharmaceutical manufacturers directly distributed the remaining 12.7% of all medicines (Table 2.12).

Pharmaceutical distribution in South Korea is managed according to the Korean Good Supply Practice (KGSP) regulations. The list of distributed medicine products needs to be submitted to the Korea Pharmaceutical Information Service (KPIS) of the HIRA according to each distribution channel. To establish good distribution practices, it is prohibited by law to sell pharmaceuticals below the acquisition cost or to conduct monopolistic sales activities for the benefit of a specific medical institution. It is also illegal for medicine distributers to provide economic benefits to physicians and pharmacists for the purpose of promoting medicines.

Table 2.12: South Korea-Medicine supply volume by distribution channel

(Units: billion KRW)

Distribution channel[1]	Distribution value		
	2012	2013	2014
Manufacturer/importer → medical care institutions, pharmacies* (direct distribution)	2,872 (14.7%)	2,499 (12.8%)	2,597 (12.7%)
Wholesalers → medical care institutions, pharmacies	16,657 (85.3%)	17,084 (87.2%)	17,922 (87.3%)
Total amount of medicines supplied to medical care institutions, pharmacies	19,529 (100.0%)	19,583 (100.0%)	20,519 (100.0%)
Manufacturer/importer → wholesaler**	14,334	14,411	15,512
Wholesaler → wholesaler	9,783	10,510	11,616

Note:1) The type of medicine supplier is classified by product category

* Manufacturer/importer → medical institution: if a manufacturer or importer supplies its own products to a medical institution

** Manufacturer/importer → wholesaler: if a manufacturer or importer supplies its own products to a wholesaler.

Source: HIRA, 2014 Medicine products distribution information statistics, 2015

Yu et al., Survey on the status of medicine wholesaler distribution and cost structure, HIRA, 2015.

[13] HIRA, 2014 Medicine product distribution statistical book, 2015

[14] Yu et al, Survey on status of Medicine wholesaler distribution and cost structure, HIRA, 2015

2.7.3 Retailers

In Korea, OTCs are sold in pharmacies and 24-hour convenience stores. Medicines sold in 24-hour convenience stores are referred to as household medicines.[15] As of 2017, it is not permitted to operate an online pharmacy. Therefore, only on-site retail pharmacies are presented in Table 2.13. In 2015, there were approximately 20,000 pharmacies that provided medicines to consumers.

Table 2.13: South Korea-Retailers of medicines, 2015

Retailers	2000	2005	2010	2015
No. of community pharmacies	n.a.	20,296	21,096	21,267
- Thereof: No. of private pharmacies	n.a.	20,296	21,096	21,267
- Thereof: No. of public pharmacies	0	0	0	0
No. of hospital pharmacies for outpatients	0	0	0	0
No. of dispensing doctors	0	0	0	0
No. of other POM disp.	0	0	0	0
Total no. of POM disp.	n.a.	**20,296**	**21,096**	**21,267**
No. of online pharmacies	0	0	0	0
No. of OTC disp., like drugstores	0	0	0	0

Disp. = dispensaries, No. = number, OTC = over-the-counter medicines,
POM = prescription-only medicines n.a. = not available

Source: NHIS, Status of medical care institutions, 2015

[15] Household medicines are OTCs that are primarily used for immediate treatment of mild symptoms. The list of household medicines is managed by taking into consideration the compound, side effect, dose, formulation, public awareness, and need for convenient purchasing. Currently, 13 products are sold at 24-hour convenience stores as household medicines.

2.8 Pharmaceutical expenditure

Pharmaceutical expenditures in Korea are estimated to be about 21.7 trillion KRW in 2014. The public sector has stabilized at 54 % - 57 %. In contrast, the private sector share decreased to 44.4% in 2005, and it has remained at 42 % - 45 % since then (Table 2.14).

Table 2.14: South Korea - Total pharmaceutical expenditure

(Units: billion KRW, %)

Category	2000	2005	2010	2014
TPE (billion KRW)	6,169	10,834	17,735	21,676
- thereof public (%)	39.3	55.6	57.5	54.6
- thereof private (%)	60.7	44.4	42.5	45.4
PE in the out-patient sector (billion KRW)	n.a	n.a	n.a	n.a
- thereof public (%)	n.a	n.a	n.a	n.a
- thereof private (%)	n.a	n.a	n.a	n.a
PE in the in-patient sector (billion KRW)	n.a	n.a	n.a	n.a
- thereof public(%)	n.a	n.a	n.a	n.a
- thereof private(%)	n.a	n.a	n.a	n.a

n.a. = not available

Source: Jeong et al. Korean National Health Accounts in 2014, MOHW, 2016.

2.9 Sources of funding

Pharmaceutical expenditures in 2014 can be divided into two categories: reimbursable medicines, which accounted for 81.3 % (16.4 trillion KRW) of total pharmaceutical expenditures, and OTCs, which made up 18.7 % (3.8 trillion KRW) of expenditures. In addition to the pharmaceutical expenditures, 7 % (1.5 trillion KRW) was spent on medical supplies. Reimbursable medicines, which accounted for the majority of spending on medicines, were mostly funded by public sources (68.5 %), while 84.2 % of OTCs were funded by private sources. Private sources also fund 99.0 % of all medical supplies.

Table 2.15: South Korea - Sources of funding for pharmaceutical expenditures, 2014

(Units: billion KRW, %)

Contents / Source funding		Total		Pharmaceutical expenditure (including dispensing fee)						Medical supplies	
				Subtotal		Reimbursable medicines[1)] (Prescribed medicines)		OTC[1)]			
		Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
Public funding	Amount	11,835	100	11,820	99.9	11,224	94.9	595	5.0	15	0.1
	%	54.6		58.6		68.5		15.8		1.0	
Private funding	Amount	98,410	100	8,340	84.7	5,159	61.9	3,181	38.1	1,501	15.3
	%	45.4		41.4		31.5		84.2		99.0	
Total	Amount	21,676	100	20,159	93.0	16,383	81.3	3,776	18.7	1,517	7.0
	%	100		100		100		100		100	

Source: Jeong et al. Korean National Health Accounts in 2014, MOHW, 2016.

Note: 1) The classification of reimbursable medicines and non-reimbursable medicines roughly corresponds to the classification of prescribed medicines and OTC under the System of Health Account.(source: Jeong et al., Scale and structure of pharmaceutical expenditure for the year 2006 in Korea, Korea Journal of Health Policy and Administration, 2008)

3 Pricing, reimbursement and volume control in the out-patient sector

3.1 Organization of the out-patient sector

Medicines in the inpatient and outpatient sectors are managed in the same manner in South Korea. Overall, as central regulatory authorities, the MFDS is in charge of medicine approval, and the MOHW is the governing body for pharmaceutical policy and reimbursement for the NHIS. The NHIS and the HIRA are tasked with the operational process of pharmaceutical reimbursement in the NHIS, and the roles of each organization are presented in section 2.1.

3.2 Pricing of medicines

3.2.1 Pricing policies

In South Korea, there are no restrictions on pricing POMs and OTCs that are classified as non-reimbursable medicines, and the patients pay 100 % of the prices of these medicines. Only, the prices of reimbursable medicines are set and publicly announced.

The prices of reimbursable medicines are determined by either price negotiations or statutory pricing that applies a preset formula (Table 3.1.) Currently, tendering is not used as a pricing mechanism.

Table 3.1: South Korea - Ways of pricing of medicines at manufacturer level, 2017

Pricing policies	(Non) prescription market		(Non) reimbursement market		Specific groups of medicine		
	POM	OTC	Reim-bursable	Non-reim-bursable	Generics	Parallel traded	Others, spec-ify: e.g. biosimilar
Free pricing	X(O)[1]	O	X	O	X	X	X
Statutory pricing	O	X	O	X	O	X	O
Pricing negotiations	O	X	O	X	X	X	X
Tendering	X	X	X	X	X	X	X

Note 1) The prices of non-reimbursable medicines are set freely by the manufacturer.

Pharmaceutical pricing mechanisms used in South Korea are explained below with a focus on reimbursable medicines that comprise 81.3% of all pharmaceutical expenditures in 2014.

In January 2007, the positive list system was introduced. The process for selecting new medicines for reimbursement under the positive list system consists of 2 pathways. The first pathway is for the DBCAC of the HIRA to evaluate the appropriateness of the new medicines for reimbursement. The Committee applies the following criteria to the reimbursement assessment. If a new medicine is cost-effective and meets other criteria listed in Table 3.2, the DBCAC of the HIRA will decide whether reimbursement of the medicine is appropriate.

Table 3.2: South Korea - Assessment of the appropriateness of reimbursement

- Clinical usefulness: substitutability, severity of disease, therapeutic benefits
- Cost-effectiveness
- Budget impact: number of patients, estimated use, etc.
- Reimbursement status, prices, and criteria in other countries
- Conditions for the manufacturer (e.g. risk-sharing conditions)
- Potential impacts on other aspects of public health

Meanwhile, new medicines that meet all the criteria listed in Table 3.2 are classified as essential medicines in South Korea. Reimbursement of an essential medicine is regarded as appropriate and acceptable based on the reimbursement status and the list price of the medicine in other countries and its budget impact, etc.

Table 3.3: South Korea - Criteria for essential medicines

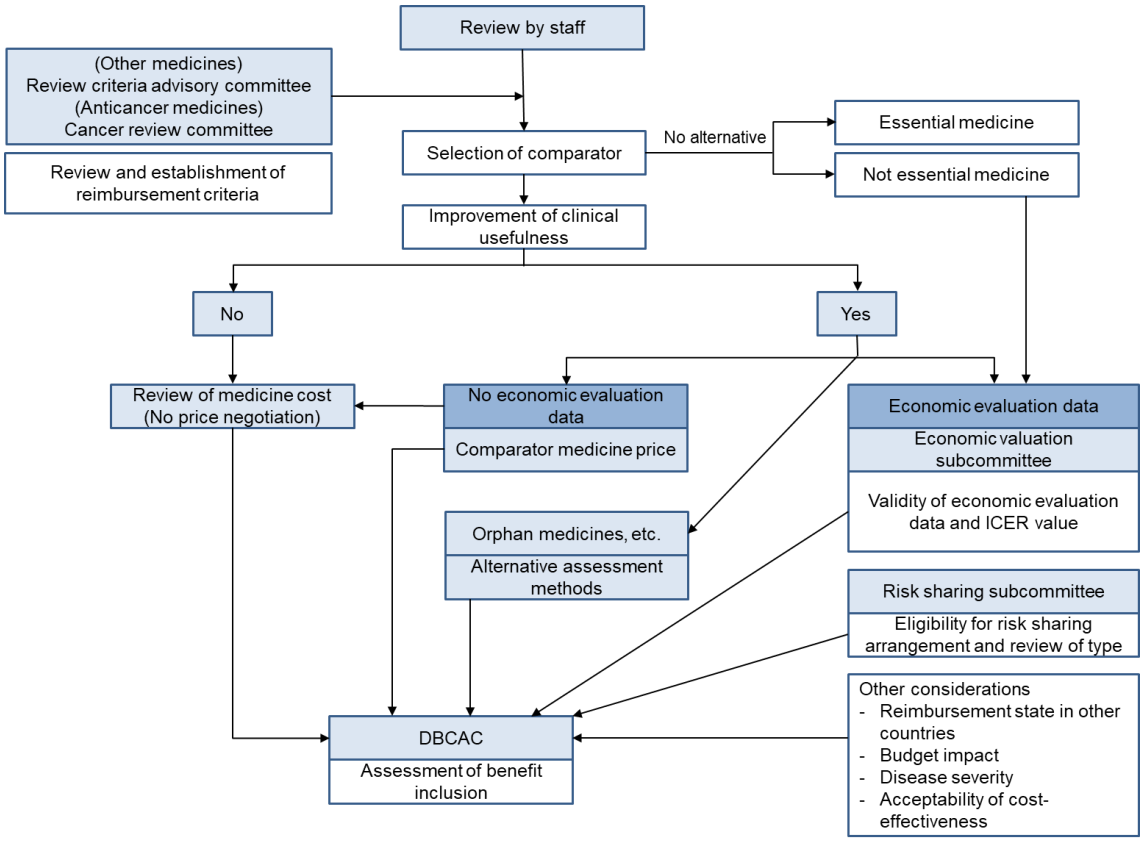
1. Medicines that meet all of the following criteria
   - Medicines for which no alternative therapies are available
   - Medicines that are used for life-threatening diseases
   - Orphan medicines that are used to treat rare diseases
   - Medicines that are proven to provide clinically significant improvements such as considerable prolongation of survival
2. Other Medicines that the Committee determines to be necessary for patient care

A controversial issue regarding the reimbursement assessment under the positive list system is the long period it takes from the time of regulatory approval of a new medicine by the MFDS to the reimbursement decision, which is over 240 days. To solve this issue, the Approval Reimbursement Assessment Link System was introduced in 2014. Through the system, the manufacturer of a new medicine can apply for the medicine's reimbursement before receiving MFDS's approval if the MOHW publicly announces that the immediate availability of the new medicine benefits the patients. In addition to expediting the process of listing a new drug, a number of other policy measures were adopted to increase accessibility to new medicines. For example, some medicines such as anti-cancer medicines are determined as reimbursable

even with a high incremental cost-effectiveness ratio (ICER). In addition, risk sharing arrangements are introduced to increase access to some medicines such as costly anti-cancer medicines and orphan medicines.[16]

Figure 3.1 shows the entire process of assessing reimbursement appropriateness of new medicines conducted by the HIRA.

Figure 3.1: South Korea - Reimbursement decision making process for medicine



Source: HIRA, National Health Insurance Drug Costs Management, 2016

The second pathway is to set the price. The prices of all new medicines are set based on negotiations, whereas the prices of generics are set by applying predetermined calculation criteria without negotiations.

The NHIS is in charge of price negotiations for new medicines. The NHIS negotiates prices with the manufacturers based on the following criteria Table 3.4.

[16] Refer to section 3.4.6. for details on risk-sharing arrangement.

Table 3.4: South Korea - Considerations of price negotiations

- Assessment by the DBCAC in HIRA
- Budget impact analysis
- Prices in foreign countries and supply capacity
- Patent status, and domestic research and development costs
- Other factors that can influence price negotiations

If the proposed price of a new biopharmaceutical and orphan medicine are equal to or lower than the weighted average price of alternative medicines, the medicine can be listed without price negotiations. Paediatric medicines can also be listed without price negotiations if the proposed price is equal to or lower than 95% of the weighted average price of alternatives. For other medicines, if the proposed price is no greater than the 90% level of the weighted average price of alternative medicines, price may be determined without price negotiations.

3.2.2 Pricing Procedures

As stated previously, listing procedures under the positive list system are comprised of two pathways. The first pathway is to assess if a new medicine should be reimbursed. The second pathway is for the NHIS and the pharmaceutical company to set the price of the medicines and its expected volume through price negotiations. A number of criteria that are presented in Table 3.4 are also considered during price negotiations. When external reference pricing is used to set the price of a new medicine, its prices in the OECD member countries with a focus on the United States, the United Kingdom, Germany, France, Italy, Switzerland, and Japan are considered.

For a newly developed domestic medicine, the cost to produce the medicine is considered during price negotiation. Since 2014, risk sharing arrangement has been implemented to increase access to expensive anti-cancer medicines and orphan medicines.[17] So far, 15 medicines were designated for risk sharing arrangements in Korea.

After the price of a medicine is publicly announced, various post hoc management systems are used to adjust the price. The primary post hoc price management system is the price-volume agreement. It was introduced in January 2007 and operated as follows. The expected volume of new medicines is set during the price negotiation process. If the actual volume of the medicines exceeds the expected volume by a certain level within a year period after its listing, then the price of the medicine will be adjusted (reduced) through renegotiations.[18]

[17] Refer to section 3.4.6. for details on risk-sharing arrangements.

[18] Refer to section 3.4.4. for details on price-volume agreement.

Medical institutions and pharmacies file claims for medicines at the actual purchase price. The weighted average actual transaction price for a year is calculated and the price of the medicines is reduced by a portion of the difference between the price and the weighted average of the actual transaction price.

Table 3.5 summarizes pricing procedures in Korea primarily used to set the prices of reimbursable medicines.

Table 3.5: South Korea-Pricing procedures for reimbursable medicines

Pricing procedure	In use	Price applied	Scope of target medicines
External price referencing	yes	Pharmacy purchasing price	Reimbursable medicines (used at negotiation)
Internal price referencing	yes	Pharmacy purchasing price	Reimbursable medicines (used at negotiation)
Cost-plus pricing	yes	Pharmacy purchasing price	Reimbursable medicines that are domestically developed (used at negotiations)
Indirect profit controls	no	n.a.	n.a.
Risk-sharing arrangement	yes	Pharmacy purchasing price	Medicines eligible for risk sharing arrangement
Price-volume agreement	yes	Pharmacy purchasing price	Reimbursable medicines
Other post hoc pricing procedures - Refund - Reducing price according to the market-based actual transaction price system - Reducing the price of the original medicine when its patent expires	yes	Pharmacy purchasing price	Reimbursable medicines

n.a.= not available

3.2.3 Specific pricing policies

A pricing policy favouring globally innovative new medicines and biosimilars has been implemented in South Korea. In particular, a biosimilar for which clinical trials are conducted in Korea

and that is manufactured by a research and development-intensive pharmaceutical company[19] may be priced at 80% of the price of the reference medicines for up to 3 years. Furthermore, a so-called “biobetter “can be priced at 100-120% of the price of the reference medicines. A double-concentration bio-pharmaceutical product can be priced at up to 1.9 times the price of its alternative low concentration formulation.[20]

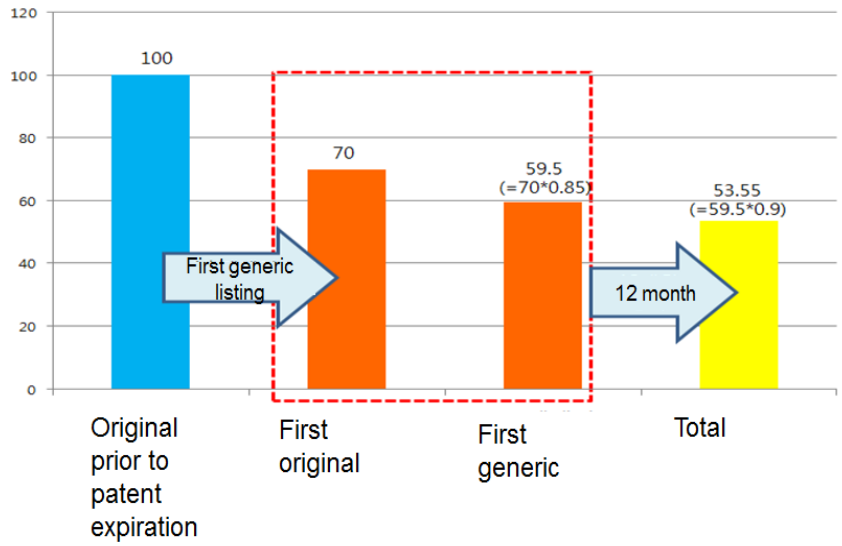
An innovative new medicine developed by a research and development oriented pharmaceutical company can be priced at a 10% premium above the price of alternative medicines and is subject to a shorter reimbursement assessment period of up to 100 days and a price negotiation period of up to 30 days. In addition, essential medicines whose marketability is too limited for companies to manufacture are designated as Shortage Prevention Medicines. The manufacturers of these medicines are compensated for costs of goods or receive production incentives.

The price of generics, which are tested for biological equivalence, is decided by the 'same compound, same price’ principle. This principle is applied differently over time to promote generics. After a first generic is listed, the price of the original medicine is set at 70% of the price prior to its patent expiry and the price of the first generic is set at 59.5% of the original medicine. If 3 or more generics are listed after 12 months, the prices of the original medicine and the generics are reset to 53.55% of the price of the original drug.

[19] Research and development-intensive companies are designated as the Innovative Pharmaceutical Companies.

[20] Other medicines of double strengths will be priced at 1.5 times the prices of low strength alternatives.

Figure 3.2: South Korea - Pricing process of generics



Source: MOHW, Press Release Legislation of the new drug-pricing policy announced; it is slated to come into effect in next Jan., 2011

3.2.4 Discounts / rebates

NHI does not have legally approved discounts or rebates form pharmaceutical companies in South Korea. Providing economic benefits, such as discounts and rebates, to medical care institutions, pharmacists or health care professionals for the purpose of inducing the adoption or prescriptions of a medicine is prohibited by law. If a medicine is implicated in a business transaction involving rebates, reimbursement for the medicine will be either stopped or the medicines will be excluded from the reimbursable medicines list depending on the number of offenses and the quantity of the medicines involved.

3.2.5 Remuneration of wholesalers and pharmacists

There is no fixed wholesale margin in Korea. Pharmacies are not allowed to charge a mark-up for medicines covered by the NHI. Instead, they receive service fees. Fees for pharmacists; services, such as dispensing, patient counselling, and pharmacy management, are determined every year through a fee agreement between the NHIS and the Korea Pharmaceutical Association. The dispensing fee, which accounts for the greatest proportion of pharmacists' service fees, increases as the number of dispensing days increases.

The price of non-reimbursable POMs and OTCs are set freely. Therefore, there is no fixed mark-up for these medicines and retail prices.

Table 3.6: South Korea - Regulation of wholesale and pharmacy mark-ups

	Wholesale mark-up			Pharmacy mark-up		
	Regulation	**Content**	**Scope**	**Regulation**	**Content**	**Scope**
South Korea	No	Domestic company (7.5-8.6%) Multinational company (3.3-5.6%)	POM	Yes	No margin	Reimbursable medicines
	No	Domestic company/multinational company (4.4-4.5%)	OTC	No	n.a	Non-reimbursable medicines, OTC

Source: Yu et al., Distribution status and cost structure of medicine wholesalers, HIRA, 2015

3.2.6 Taxes

The 10% value added tax rate applies to medicines as well as other products.

3.3 Reimbursement of medicines

3.3.1 Reimbursement policies

In South Korea, reimbursable medicines include not only POMs but also OTCs. However, a large number of OTCs are non-reimbursable. In addition, most preventive vaccines are not reimbursable.

The medicine reimbursement assessment is a process which selects medicine with good clinical and economic benefits. Among all criteria shown in Table 3.1, the most important one is economic evaluation data.

Economic evaluation methods recommended by the Guidance on Economic Evaluation of Medicines in South Korea[21] are cost-minimization, cost-effectiveness, and cost-utility analyses. If a new medicine has superior effectiveness, cost-effectiveness or cost-utility analysis is recommended. If quality of life is a primary outcome and the purpose of the analysis is to compare

[21] HIRA, Guidance on Economic Evaluation of Medicines and reporting manual, 2011

different health outcomes, cost-utility analysis is recommended to provide quality-adjusted life years (QALYs). The final outcome of cost-effectiveness and cost-utility analyses is presented in terms of ICER, which indicates the additional costs required to produce one additional unit of effectiveness (1QALY) compared to alternative therapy. Although no clear ICER threshold value is established in South Korea**,** currently around 1GDP is adopted as the ICER threshold. The ICER threshold used to make a reimbursement decision of a new medicine is set by taking into account per capita GDP as a basic reference value and in addition by considering disease severity and societal disease burden.[22]

The NHIS proceeds with price negotiations. In that process, the NHIS determines the price with the manufacturer by taking into consideration the various information described in Table 3.3. The agreed-upon price is then reported to the MOHW, which then issues a public notice of the price after a review by the Health Insurance Policy Council (HIPC).

When health care providers file claims for medicine costs to the NHIS, they do not use the price but actual acquisition cost. Therefore, only drug acquisition costs without distribution margin are reimbursed.[23] The weighted average of the actual transaction price of a product is calculated during a specific period, which will then be used to cut the maximum price for the product. Under the scheme, a subsequent drug price adjustment will be made to the degree to which health care providers lower the drug acquisition price. An incentive is provided for medical institutions and pharmacies to promote procurement of medicine at lower prices. This policy is designed to provide part of the expected cost savings (price minus acquisition cost) as an incentive to health care providers when they procure medicine at lower prices than the price. This incentive is paid as part of the 'Incentive Program for Drug Cost Saving,' which will be described later on this report.

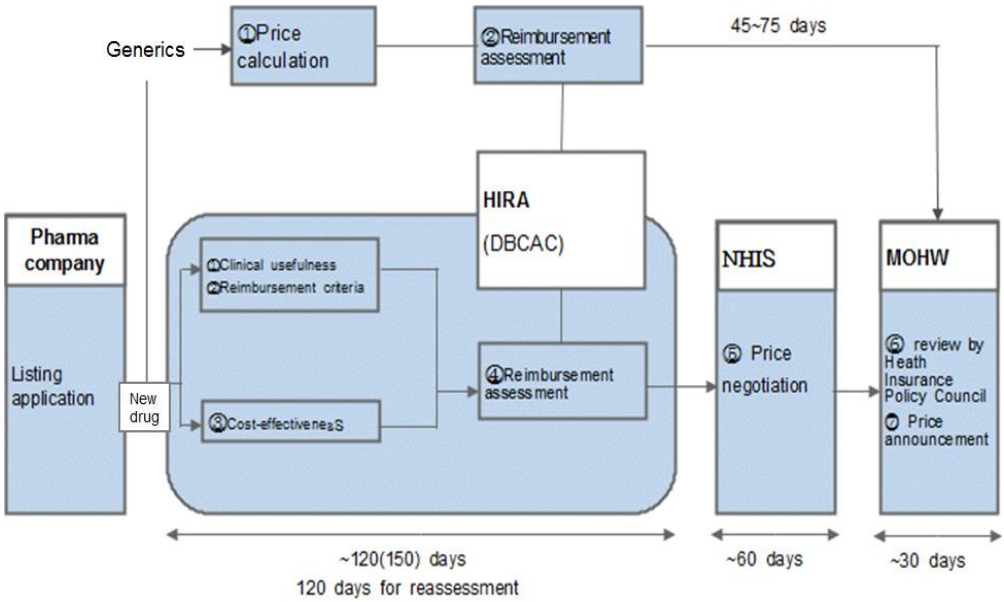
3.3.2 Reimbursement procedure

The entire listing and pricing procedures for new medicines in the NHI system are illustrated in Figure 3.3.

[22] Yoo, Medicine reimbursement appropriateness through clinical usefulness and cost-effectiveness review, Health Industry Trend, KHIDI, 2013

[23] If drug acquisition cost is greater than the price, the price is regarded as the acquisition cost. (The National Health Insurance Act, Implementation Orders, Article 22)

Figure 3.3: South Korea - Medicine reimbursement decision making process



Source: MOHW, Regulations on Reimbursement Criteria for National Health Insurance, 2014

The first step is for the DBCAC of the HIRA to assess if a new medicine should be reimbursed by the NHI. During this step, various criteria presented in Table 3.1 are reviewed. Generally, the reimbursement assessment can take up to 120 days from HIRA's review of a submission to reimbursement decision making. If the applicant disagrees with the result, it can apply within 30 days for a reassessment or an independent review.[24] The HIRA then conducts the reassessment within 120 days.

Once a medicine is determined to be appropriate for reimbursement, the NHIS proceeds with price negotiations to set the price and expected volume. Multiple price negotiations are conducted during a 60-day-period between the NHIS and the pharmaceutical company. If the price of the medicine is agreed upon, it is reported to the MOHW and followed by a review by the Health Insurance Policy Council (HIPC); the price is decided and publicly announced by the MOHW within 30 days.

In order to be reimbursed for the costs of prescribing and dispensing medicines listed on the formulary, health care providers file claims of which over 95% are submitted electronically. Multi-step reviews involving staff reviewers and a review committee in the HIRA are conducted

[24] The independent review process is a process carried out by the MOHW in which the reimbursement are reviewed independently of the MOHW, the NHIS, and the HIRA. The MOHW should convene an independent review commission: The report of an independent review should be submitted within 150 days.

and when completed, results are compiled and reported to the NHIS. The NHIS combines all claims and pays the total amount per health care provider.

3.3.3 Reference price system

A reference price system is not implemented in Korea.

3.3.4 Private pharmaceutical expenses

Cost-sharing for services reimbursed by the NHI is summarized in Table 3.6. Out-of-pocket payments are charged for total medical care expenditure and the criteria for cost-sharing for medicines are not designated separately. National Health Insurance beneficiaries pay approximately 30% of total costs for outpatient prescriptions and 20% of total costs for inpatient care. Patients with severe diseases such as cancer and cerebrovascular diseases that incur high medical care expenditure may have reduced out-of-pocket payments, which are only 5%-10% of total costs. Patients aged 65 years and older are eligible to pay a fixed co-payment per visit. Beneficiaries of Medical Aid pay a co-payment of 500 KRW per each prescription dispensed at pharmacies irrespective of total pharmaceutical expenditures, and 10 % of total medical expenditures for inpatient care.

Table 3.7: South Korea - Cost-sharing for medicines, 2017

Category	Cost-sharing	Amount	Target group
National Health Insurance	Statutory coinsurance	• On average, 30% of prescription medicines dispensed at pharmacies • On average, 20% of total medical expenditure for inpatient care	• National Health Insurance beneficiaries
	Co-payment	• Fixed amount of 1,200 KRW if total medical care costs are no more than 10,000 KRW	• Elderly aged 65 years and older
	Reduced coinsurance rate	• 5%-10% of prescription drug costs dispensed at pharmacies • On average, 5%-10% of total medical expenditures for inpatient care	• Patient with cancer, cardiovascular disease, cerebrovascular disease, or rare refractory disease, children under 6 years
Medical Aid		• Co-payment of 500 KRW for dispensing of outpatient prescriptions • 10% coinsurance for inpatient care	• Beneficiaries of Medical Aid types 1 and 2

3.4 Volume control

3.4.1 Generic substitution

In South Korea, if a pharmacist intends to substitute a prescription medicine with another medicine, the pharmacist needs to get consent from the prescriber in advance. However, if the pharmacist substitutes a medicine with another medicine with the same compound, dose, and formulation and with proven bioequivalency, he/she does not need prescriber's consent in advance but only needs to notify the prescriber within a day.

A substitution incentive system was implemented under the NHI to increase the use of cheaper generics by promoting substitution. If a prescribed medicine is substituted with another bioequivalent, cheaper medicine, the pharmacist will obtain 30% of the price difference between the prescribed and the substituted medicines as an incentive. Despite the incentive system, however, the rate of generic substitution in Korea was only 0.12% in 2015.[25] The administrative burden associated with notifications of generic substitution to prescribers and their low confidence in bio-equivalent data of generics were among the reasons for the low substitution rate.[26]

3.4.2 INN prescribing

Currently, prescriptions may be written in either a brand name or generic name in Korea. However, most prescriptions are written in brand names.

3.4.3 Other generic promotion

Besides the generic substitution incentive program, the Incentive Program for Medicine Cost Saving was implemented to promote the use of generics. The aim of this program is to promote the reduction of pharmaceutical expenditures. Under this incentive program, medical institutions and pharmacies can receive an incentive when they reduce medicine costs by substituting with cheaper alternatives or purchasing medicines at lower prices. The total incentive amount to medical institutions is a sum of the incentive for purchasing medicines at lower prices and the incentive for the reduction of medicine use.

The incentive for purchasing medicines at lower prices is calculated by multiplying savings due to low cost purchasing by the payment rate per institution. Savings are derived from the difference between the price of a medicine and its actual purchasing cost.

[25] HIRA, Review decision of health insurance pharmacy substitution (yakup.com)

[26] Lee et al., Current status of bio-equivalence test and policy measures to increase bio-equivalent pharmaceutical products, MFDS, KIHASA, 2003

The incentive for reducing use of medicines is calculated by multiplying savings due to reductions of medicine use by the payment rate per institution.[27] Savings are calculated as the difference between prescription medicine expenditures for patients with the same disease category in the same age group between the previous year and this year.

The reduction of pharmaceutical expenditures is evaluated by the HIRA every 6 months and incentives are paid accordingly.

3.4.4 Claw-backs

A price volume agreement (PVA) was introduced in South Korea in January 2007 in order to manage risk in the health insurance budget due to increased use of medicines. The key feature of this policy is volume-price negotiations. The pharmaceutical company and the NHIS agree on an expected volume of a medicine during the price negotiation process, but they renegotiate to adjust the medicine price if the actual volume for the medicine during a certain period exceeds the expected volume. In addition, the price of a medicine that is already listed will be adjusted through negotiation if the volume of the medicine increases excessively. The negotiation criteria apply to the claimed volume, not per product but per therapeutic class.[28]

There are three types of price volume agreements as shown in Table 3.8. Meanwhile, medicines that are expected to have little effect on insurance budget saving through price-volume negotiations, such as medicines that are designated as Shortage Prevention Drugs, inexpensive medicines, and medicines with an annual claim amount of less than 1.5 billion KRW, are excluded from the PVA.

[27] The payment rate varies depending on the prescribing costliness index (PCI). The PCI represents pharmaceutical spending at a medical institution relative to those at other similar institutions. If the PCI at a hospital is greater than 1, pharmaceutical spending at the hospital are greater than the national average.

[28] Medicines with the same manufacturer, route of administration, compound, and formulation

Table 3.8: Types of price-volume agreements, 2017

Type	Application criteria	Monitoring		Analysis period
		initiative	cycle	
Type A	• If the claim amount in the same therapeutic class exceeds the expected claim amount by over 30%	NHIS	Monthly	• 1-year period from the date when the first medicine in a therapeutic class is listed every year
Type B	• medicines in a therapeutic class for which the maximum price is adjusted according to type A, and if the amount increases by over 60% from the previous year's amount, or if the rate of increase is over 10% and the amount is 5 billion KRW	NHIS	Monthly	• 1-year period from the date when the maximum price for a therapeutic class is adjusted according to type A every year
Type C	• medicine in a therapeutic class that are listed without negotiations, if the amount increases by over 60% from the previous year's amount, or if the rate of increase is over 10% and the amount is 5 billion KRW	NHIS	Yearly	• From January 1 to December 31

Source: NHIS, Drug cost policy handbook, 2016

3.4.5 Refund system

Two types of refund systems are in place in Korea. The first type is the price-volume-based refund system that has been implemented since 2015. This system was introduced to support domestically developed new medicines with a view to entering the global market. For these medicines eligible for this system, a price reduction according to the price-volume agreement will be postponed for 3 years, after which a certain amount will be refunded to the NHIS. Medicines currently eligible for a refund agreement include new medicines and cell therapies that are developed by innovative pharmaceutical companies.

The second type is a pilot project for essential medicines used for the treatment of rare refractory diseases. This system was developed to prepare for the scenario when price negotiations fail or when the suppliers of essential medicines refuse to supply medicines at low prices. In this project, the price demanded by the pharmaceutical company will be listed and the difference between the listed price and the actual price will be refunded. This pilot project ran from August 2009 to September 2015. After the pilot project finished, the medicines eligible for the project were included into risk sharing arrangements through assessment by the DBCAC and negotiations with the NHIS.

3.4.6 Risk sharing arrangement

The risk sharing arrangement system was designed to share risk associated with the therapeutic efficacy and budget impact of a new medicine between the payer and the manufacturer. The system was introduced in 2014 for anti-cancer medicines and orphan medicines. There are four types of risk sharing arrangements that are being carried out: conditional treatment continuation combined with money back guarantee; expenditure cap; refund; utilization cap/fixed cost per patient (Table 3.9).

Table 3.9: South Korea – Types of risk sharing arrangement

Type	Key content
Conditional treatment continuation and money back guarantee combination	• Responders continue to be treated with the medicine but the cost of the medicine for non-responders is refunded.
Expenditure cap	• The pharmaceutical company refunds a proportion of actual volume in excess of the cap to the NHIS.
Refund	• The pharmaceutical company refunds a proportion of total claim amount to the NHIS.
Utilization cap/fixed cost per patient	• A utilization cap per patient is set. A proportion of claim amount in excess of the cap will be refunded to the NHIS.

Source: HIRA, Evaluation standards for negotiation medicine including new drug, 2016

Under the positive list system, the process of assessing medicines for risk sharing arrangement is almost the same as that of assessing new medicines in general. First, if a pharmaceutical company applies for a reimbursement assessment of a new medicine with a risk sharing arrangement, the DBCAC will determine if the medicine is eligible for a risk sharing arrangement. There are two criteria for determining eligibility. The first one is the anti-cancer medicines and orphan medicines for life-threatening diseases or when there are no substitutable alternatives or therapeutic equivalents. The second one is determined by the DBCAC on the basis of disease severity and societal impact on public health. If a new medicine is determined appropriate for reimbursement, the NHIS reviews the risk arrangement plan submitted by the pharmaceutical company and proceeds with negotiations for the price and refund rate. The basic contract period for risk sharing is 4 years (3 years plus 1 year for evaluation) and may be extended up to 5 years on a case-by-case.

Risk sharing arrangements (RSA) were started for a total of 15 medicines: refund for 9, expenditure cap for 4, coverage with evidence development for 1, and utilization cap/fixed cost per patient for 1. Medicines applied to RSA were either anti-cancer medicines or orphan medicines.

Table 3.10: South Korea - Medicines on risk sharing agreement, June 2017

No.	Medicine name	Type	Indication
1	Lenalidomide	Refund	Multiple myeloma
2	Cetuximab	Refund	Metastatic colon and rectal cancer, head and neck cancer
3	Enzalutamide	Refund	Metastatic prostate cancer
4	Crizotinib	Refund	Non-small cell lung cancer
5	Pirfenidone	Refund	Idiopathic pulmonary fibrosis
6	Eculizumab	Refund	Paroxysmal nocturnal hemoglobinuria
7	Galsulfase	Refund	Mucopolysaccharide
8	Regorafenib	Refund	Gastrointestinal stromal tumor
9	Pomalidomide	Refund	Multiple myeloma
10	Vandetanib	Expenditure cap	Medullary thyroid cancer
11	Elosulfase alfa	Expenditure cap	Mucopolysaccharide
12	Saproterin	Expenditure cap	Phenylketonuria
13	Edifbrotide	Expenditure cap	Hepatic veno-occlusive disease
14	Clofarabine	Coverage with evidence development	Pediatric acute lymphoblastic leukemia
15	Pertuzumab	Utilization cap/fixed cost per patient	Breast cancer

Source: National Health Insurance Service, 2017

3.5 Evaluation

3.5.1 Prescription monitoring

The predominant forms of prescription monitoring in South Korea are the evaluation project on appropriate prescribing and the Drug Utilization Review system (DUR). The evaluation project

on appropriate prescribing is a system of analysing outpatient prescription patterns in a medical institution, clinical specialty, and region by using electronically submitted claims data.[29] The indicators of appropriate prescribing are as shown in Table 3.11. Since 2014, economic incentives are provided to medical institutions on the basis of three indicators such as the prescription rate of antibiotics for acute upper respiratory tract infection, the prescription rate of injectables, and the prescription rate of 6 or more medicines per prescription. The assessment results are published on HIRA's web site[30] to inform patients and their health care providers.

Table 3.11: South Korea - Indicators of the appropriateness of prescribing, (insert year pls)

Category	Indicator
Evaluation indicator	• Prescription rate of antibiotics for acute upper respiratory tract infection
	• Prescription rate of third and newer generation cephalosporin antibiotics for acute upper respiratory tract infection • Prescription rate of quinolone antibiotics for acute upper respiratory tract infection
	• Prescription rate of injectables
	• Number of medicine items per prescription (all diseases) • Prescription rate of 6 medicines and more per prescription
	• Medicine costs per day
	• Duplicate prescription rate of NSAIDs • Prescription rate of adrenocorticosteroids
Monitoring indicator	• Prescription rate of antibiotics for all diseases • Prescription rate of antibiotics for respiratory diseases • Prescription rate of antibiotics for respiratory disease excluding acute upper respiratory tract infection

Source: HIRA, Reimbursement appropriateness assessment plans, 2016

The DUR system is designed to prevent inappropriate medicine usage and adverse medicine events by reviewing prescriptions in real time at the point of prescription and dispensing for various criteria such as age-based and pregnancy-based contraindications through HIRA's computerized prescription review system.[31] The system provides a pop-up alert in case a prescription has an issue.

[29] Claims for over 95% of outpatient prescriptions are filed electronically.

[30] www.hira.or.kr

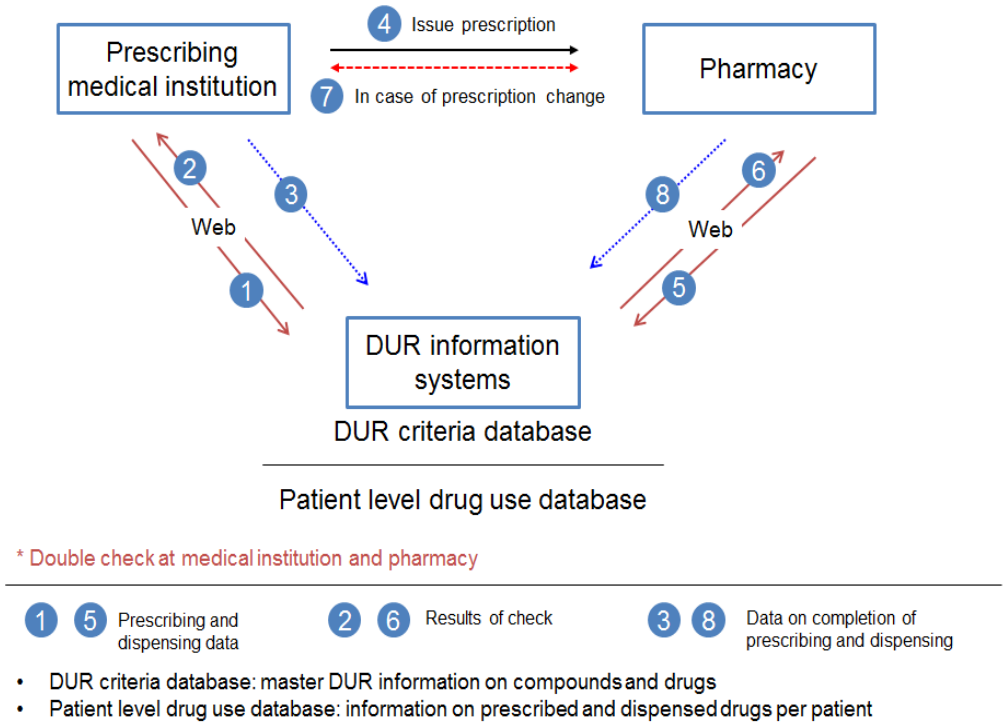
[31] Cited from the information on DUR system released by Health Insurance Review and Assessment Service, 2015

The DUR program covers all healthcare institutions and all beneficiaries of the NHIS and the Medical Aid program. The DUR program includes all medicines prescribed or dispensed in the outpatient setting.

The DUR performs two kinds of checks: one is within each prescription and another is cross-check across different prescriptions. Information checked within individual prescriptions includes drug-drug interactions, age-based contraindications, pregnancy-based contraindications, and duplicate medicines. Under the DUR program, prescriptions are inspected twice: first by medical institutions and secondly by pharmacies.

The actual DUR checking process is shown in Figure 3.4. First, information on a prescription is transmitted to the HIRA at the prescribing stage and then the HIRA checks it against the patient-level information database and the DUR criteria database and transmits it back to the medical institution. The prescriber can change the original prescription based on the results of the check or override the popup alert if the original prescription is necessary by citing a reason for maintaining the original prescription. Next, when dispensing a medicine, the pharmacist transmits the information on the prescribed medicine to the HIRA, where similar checks are performed.

Figure 3.4: South Korea - Drug Utilization Review system



Source: MOHW, Drug Utilization Review manual, 2015

3.5.2 Pharmaceutical consumption monitoring

Pharmaceutical consumption monitoring by region, patient, or diagnosis is not conducted in Korea.

3.5.3 Decision making tools

Economic evaluation has been used as the primary decision making tool since the positive list system was implemented in January 2007. Medicines that are subject to economic evaluation are those for which alternative medicines are available and with improved clinical usefulness compared with the alternatives. Economic evaluation of medicines in South Korea is operated according to the guideline on economic evaluation published by the HIRA. The guideline recommends that if there are multiple alternative medicines, the most frequently one used should be used as the comparator. A commonly used analytical technique is cost-utility analysis that measures health outcomes in terms of QALY. Cost-minimization analysis is conducted if a new medicine has the same effectiveness as the comparator.

A limited societal perspective is recommended in economic evaluation in South Korea. Therefore, the scope of cost calculation includes not only direct medical costs associated with medicines, physician consultation, dispensing, and diagnosis, but also direct non-medical costs such as transportation costs. However, in case of the cost of lost productivity, the methodology to measure the cost remains controversial and the resulting value may vary considerably depending on the costing technique. Due to its measuring uncertainty, the cost of lost productivity is not recommended to be included in the basic analysis. In principle, domestic data are needed for economic evaluation analysis.

The guideline recommends that 5% is used as the basic discount rate and that sensitivity analyses are performed by using discount rates of 3% and 7% to confirm the robustness of the ICER produced.

There is no clearly set threshold for ICER in South Korea but reimbursement decisions are made based on GDP per capita. However, some medicines such as anti-cancer medicines may receive a favorable reimbursement decision by the DBCAC despite having high ICER values.

4 Pricing, reimbursement and volume control in the in-patient sector

4.1 Organization of the in-patient sector

As stated previously, a separate pharmaceutical management system for inpatients does not exist in Korea. Therefore, organizations associated with pharmaceutical management and their roles are as described in section 2.1. Payments for inpatient care and prescription medicine costs under NHI are made according to a fee-for-service system. However, payments for 7 disease groups such as cataract and tonsil surgery are made according to the diagnosis-related group (DRG) system.

4.2 Pricing and purchasing policies

Pharmaceutical price and purchasing policy is generally the same in the inpatient and outpatient sector, with the exception that tertiary hospitals mostly purchase medicine through bidding, whereas hospitals, clinics or pharmacies, purchase medicines from pharmaceutical companies and wholesalers. Tertiary hospitals select and contract with the wholesalers who will supply needed medicines at the lowest price among wholesalers that submit bids. The acquisition price will include a 10% value added tax (VAT) and wholesale margin. Since inpatient pharmaceutical expenditure is also eligible for 'Incentive Program for Drug Cost Saving', medical institutions are motivated to purchase medicines at a price lower than the upper price limit. In other words, medical institutions try to reduce the purchase price because the financial incentive they receive increases depending on the difference between the upper price limit and the actual purchase price.

4.3 Procurement

Medicines for inpatients as well as those for outpatients can be purchased from pharmaceutical companies directly or from wholesalers. Orphan medicines can be purchased from the Korean Orphan Drug Center.

4.4 Reimbursement

In South Korea, medicine payment policy for inpatients is not different from that for outpatients (refer to section 3.3.). Claims for inpatient medicine use must be filed for actual transaction costs (acquisition costs) excluding distribution margins.

However, co-payment can differ between inpatients and out patients. In general, patients pay 20 % of total costs for inpatient care and 30 % for outpatient care.

4.4.1 Hospital pharmaceutical formularies

The list of medicines reimbursable under NHI in South Korea is uniformly applied nationwide. As previously described, approximately 20,000 medicines are included in the list in 2017. Among the list, each hospital establishes and uses its own formulary that comprises of only medicines that are used at the hospital. The formulary is established by a medicine committee at the hospital.

4.4.2 Pharmaceutical and Therapeutic Committees

Antibiotics are known to be overused and abused in South Korea. For that reason, the government recommends hospitals to form and operate an antibiotic subcommittee for antibiotic use management. In general, the subcommittees consist of infectious disease specialists, clinicians that often use antibiotics at the hospital, and pharmacists. They monitor antibiotics use patterns for inpatients and develop and publish guidelines on antibiotics use.

4.5 Volume Control in the in-patient sector

4.5.1 Monitoring

While the DUR and the assessment of drug reimbursement appropriateness are implemented for outpatients, no nationwide monitoring program is developed specifically for inpatients. However, the pharmacy department at many hospitals voluntarily conduct monitoring for inpatient. The contents of prescribing monitoring provided by hospital pharmacists, as the contents of the DUR system, include patient's history of medicine use, prescribing of age-contraindication and medicine - medicine interaction, and duplicate prescription of the same compound or the same medicine class.

4.5.2 Decision-making tools

Economic evaluation is used as a decision-making tool for the reimbursement of medicines for inpatients under the positive list system. Details are described in section 3.5.3.

4.5.3 Evaluation of measures

There is no specific evaluation system for inpatients.

4.5.4 Reports and results

There is no specific reporting of evaluation results for inpatients.

5 Interface management and developments

5.1 Interface management

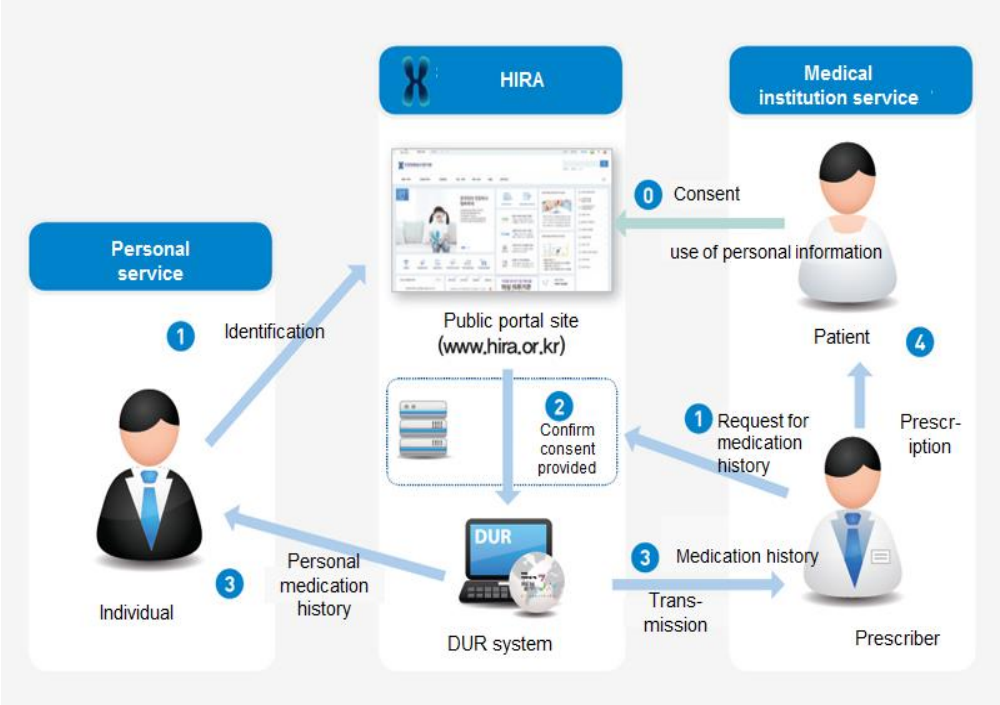
In Korea, there is no system of exchanging information on prescriptions between medical institutions. However, the NHIS and the HIRA operate two medicine information management systems in order for patients to identify the medicines they take and get information on the medicines.

First, the NHIS runs the medicine management system as part of the 'Health iN' service. All outpatient and inpatient prescriptions are included. Patients will be provided information on the following: the date of visit to medical institutions and pharmacies in the last year, number of prescriptions, prescribed days, and brand name and strength of medicines taken in the previous year. Patients also obtain information on the indications, dosage and use, side effects, medicine interactions of the medicine they were prescribed.

Another system ('My prescription medicine! at a glance' service) is run by the HIRA. This system allows patients to see the 3-month medication history. This service includes only outpatient prescriptions dispensed at community pharmacies that are collected by the HIRA's DUR system.

This information may be provided to health care providers if the patient gives consent (Figure 5.1).

Figure 5.1: South Korea - 'My prescription medicine! at a glance´service procedure

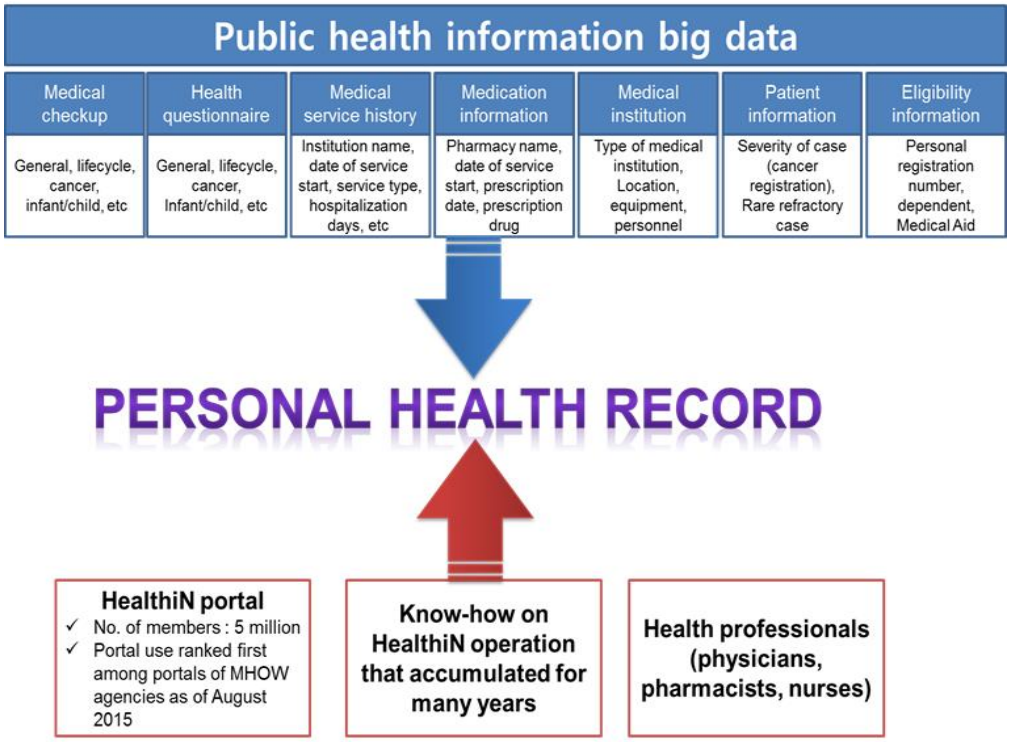


Source: HIRA, 'My prescription medicine! at a glance' service procedure, 2016 (http://www.hira.or.kr/rg/dur/indvAgreeNew.do?pgmid=HIRAA050300000000#)

5.2 Developments

Korea has abundant electronic databases such as the NHI database and the elderly long term care database. By linking these data sources, the public sector leads the efforts to develop these into personal health record format and to systematically provide necessary information to individuals in order to collect and manage various information needed for their own health management.

Figure 5.2: South Korea - Establishment of health information data for individual patients



Source: NHIS, Health in service report, 2015

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