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Building D, 370 Sicheong-daero, Sejong City 30147 KOREA **Korea Institute for Health & Social Affairs**

Characteristics of New Drugs Approved in Korea in 2007~2018

Sylvia Park
Research Fellow, KIHASA

Sol-Leep Ha
Senior Researcher, KIHASA

Introduction

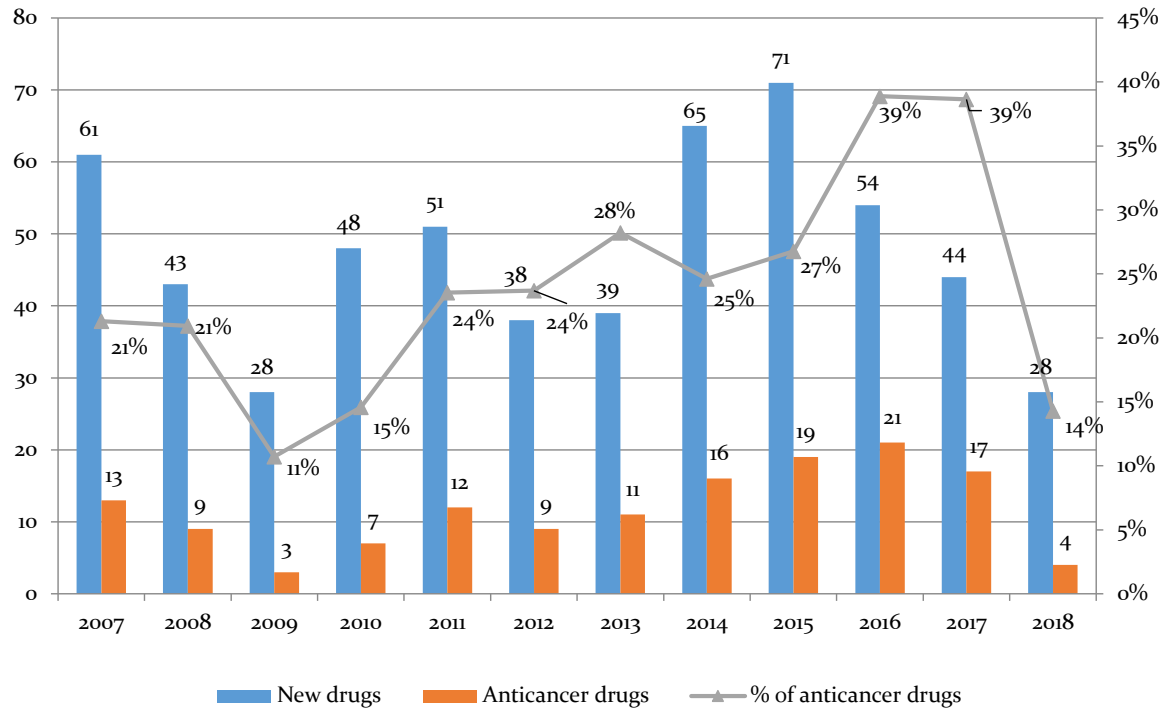
As medicinal technologies continue to advance, the development of new drugs, especially those targeting serious conditions like cancer and rare diseases, has been on the global rise. These high-priced specialty drugs account for an increasing share of pharmaceutical expenditure. Also, facilitating the availability of new drugs has become a subject of growing attention, and new methods of ensuring prompt availability of new drugs, such as accelerated approval and risk-sharing arrangements (RSAs), have been used widely around the world. With the reliance on fast-track approvals growing, however, the evidence on which to base reimbursement decisions is becoming increasingly uncertain.

This study examines new drugs that were approved in Korea in the years from 2007 to 2018, focusing on their therapeutic innovation, how many of them are cancer medicines, whether they are on RSAs, how many of them are on the National Health Insurance reimbursement list and how much is spent on reimbursing them. The drugs examined in this study are 570 medicinal products that were approved by the Ministry of Food and Drug Safety as new (or orphan) drugs and remained approved as of January 2019. In this study, the term “new drugs” include drugs with orphan designation.

General features of new drugs approved in the years 2007~2018

During the years from 2007 to 2018, an annual average of 47.5 new drugs were approved. The year with the most number of new approved drugs (71) was 2015. Anticancer drugs numbered 141, accounting for 24.7 percent of all new drugs. The share of anticancer drugs rose over time to reach 39 percent in 2016 and 2017.

[Figure 1] New drugs and new anticancer drugs, by year



Of the 570 new drugs, 311 were identified as having been approved by the US Food and Drug Administration; 276 products came with information on their innovation status from France's Haute Autorité de Santé (HAS). Of the 311 drugs that were identified in the FDA system, 44.7 percent were found to have undergone a priority review process. As for the drugs identified in the HAS database, 27.5 percent were those granted with grades I, II, and III for their improved therapeutic benefits (Table 1). The proportion of new drugs recognized as innovative grew from 2007 to 2012, and then declined rapidly afterward in both the FDA and HAS systems. The proportion of priority-review drugs increased rapidly over the years, while the proportion of new products given grades I~III grew rather moderately (Figure 2).

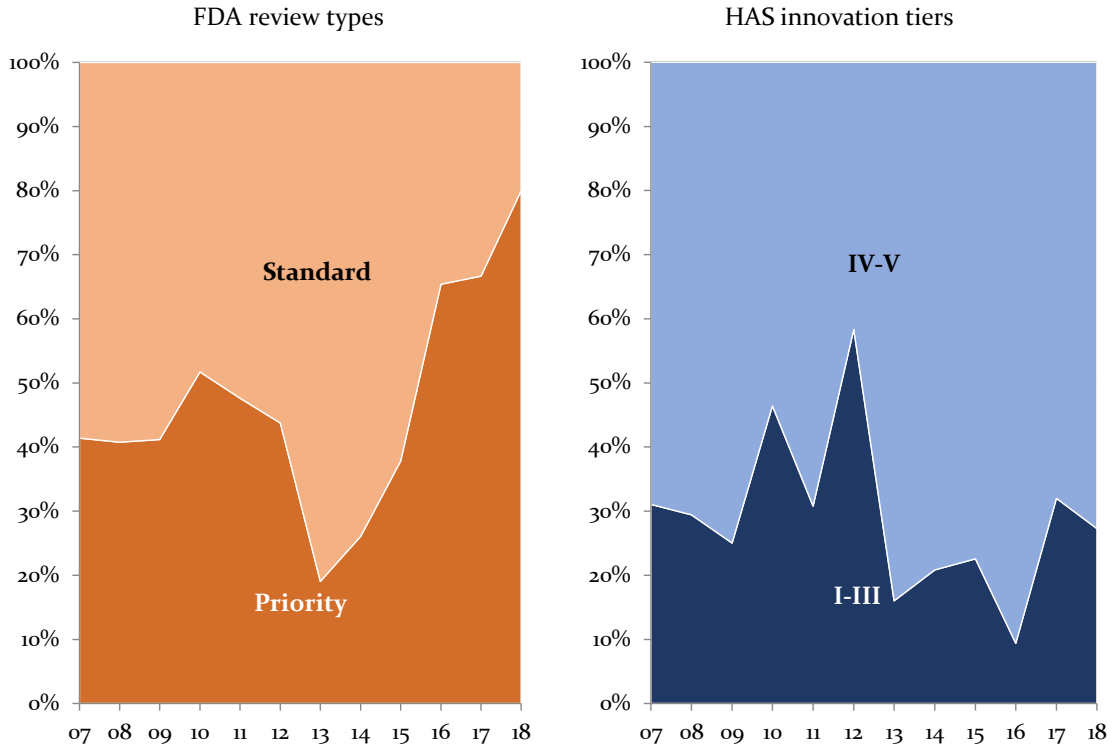
The proportion of drugs classified as innovative was larger in anticancer drugs than in all new drugs (see Table 1). Priority-review drugs accounted for 64.8 percent of the FDA-reviewed anticancer drugs; 42.9 percent of the anticancer drugs assessed by the HAS were of grades I~III. The outcomes differ presumably because the two review systems concerned have different goals and criteria. The main aim of the FDA's priority review is to prioritize the review of new drugs that are in urgent need, whereas ASMR

is aimed at setting reimbursement levels and prices for new drugs after they are approved for marketing. For this reason, ASMR can be more restrictive.

[Table 1] Assessment of therapeutic innovation: US FDA vs. France's HAS

	US FDA review			France's HAS (ASMR rating)		
	Priority review	Standard review	Total	I~III	IV~V	Total
New drugs	139 (44.7%)	172 (55.3%)	311 (100%)	76 (27.5%)	200 (72.5%)	276 (100%)
New anticancer drugs	59 (64.8%)	30 (33.7%)	89 (100%)	30 (42.9%)	40 (57.1%)	70 (100%)

[Figure 2] Types of therapeutic innovations, by year



Of the 570 new drugs examined, 67.2 percent were on the NHI reimbursement list as of May 2019 (Table 2). For the years 2013~2015, over 70 percent of approved new drugs were listed as reimbursable. This can be thought of as due to the policy of expanding the coverage of the National Health Insurance (Figure 3). NHI-listed drugs as a share of new drugs approved in and after 2016 were relatively low, one reason for which may be the time it takes for new drugs to enter the reimbursement list after their market approval. An observation at a later time may show a higher percentage of reimbursable drugs.

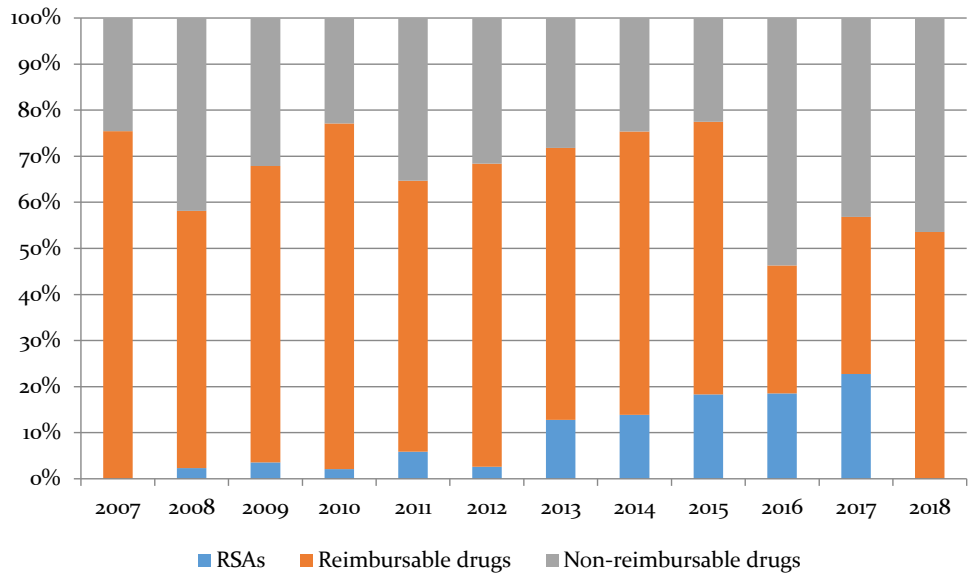
Of the 141 anticancer drugs, 99 (70.2 percent) were on the reimbursement list (Table 2). As for the anticancer drugs approved in 2013~2015, about 90 percent were listed as reimbursable. Reimbursable products as a share of the anticancer drugs approved in and after 2016 may increase at a later time (Figure 4).

Close to half (45.5 percent) of the new anticancer drugs were on RSAs; 14.1 percent of all new drugs on the reimbursement list were listed with RSAs.

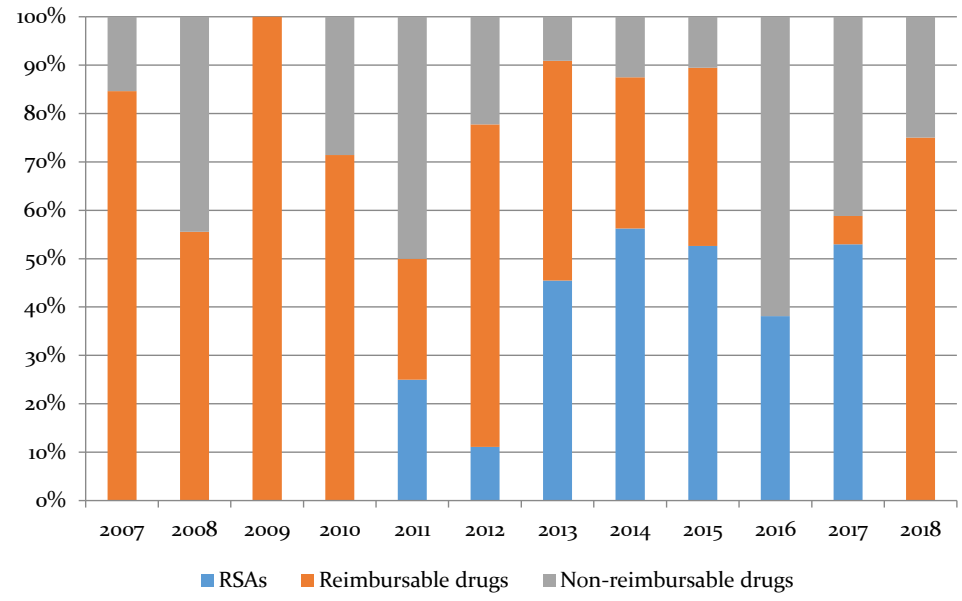
[Table 2] New drugs on the NHI reimbursement list, in number and %

	Total	NHI-listed	NHI-listed via RSAs
New drugs	570	383 (67.2%)	54 (14.1%)
New anticancer drugs	141	99 (70.2%)	45 (45.5%)

[Figure 3] Reimbursable drugs as % of new approved drugs, by year



[Figure 3] Reimbursable drugs as % of new approved drugs, by year



Those granted accelerated approval (or conditional marketing authorization in the case of EU countries) accounted for 66.7 percent of drugs that were listed with RSAs, 46.8 percent of anticancer drugs, and 15.4 percent of all new drugs (Table 3). Most of the new drugs approved for marketing in Korea were first developed in and imported from other countries. These drugs, having been granted accelerated approval in the US or conditional marketing authorization in European countries, were likely to have been granted marketing approval in Korea through a conditional authorization process. The share of drugs with accelerated (or conditional) approval has increased in recent years. That new drugs on RSAs include a high percentage of drugs with accelerated approval is as expected, as requirements for accelerated approval are similar to those for RSAs. It should be noted, however, that uncertainties remain as to the effectiveness of products that are marketed through accelerated approval until conclusive clinical evidence is found that shows their effectiveness.

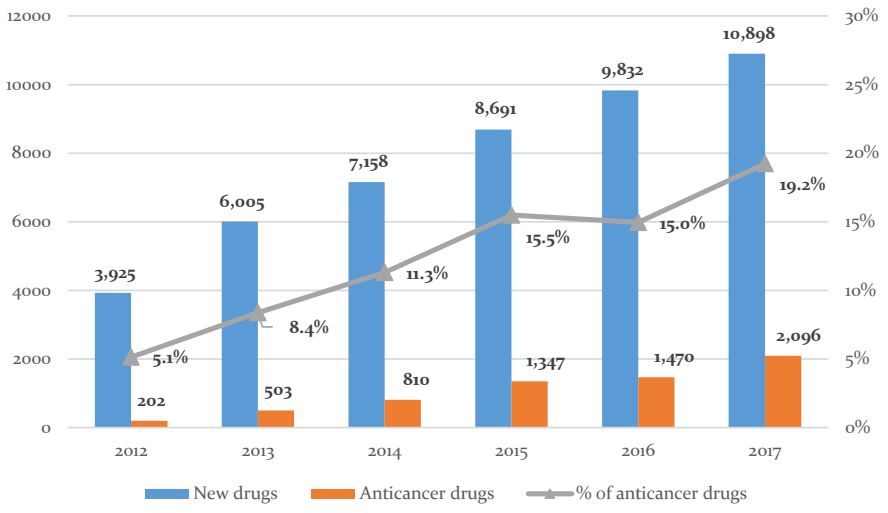
[Table 3] Drugs with the US's accelerated approval or the EU's conditional marketing authorization

	Total number	Drugs granted accelerated approval or conditional marketing authorization	
		Number	%
New drugs	570	88	15.4
New anticancer drugs	141	66	46.8
Drugs with RSAs	54	36	66.7

NHI expenditures on new drugs

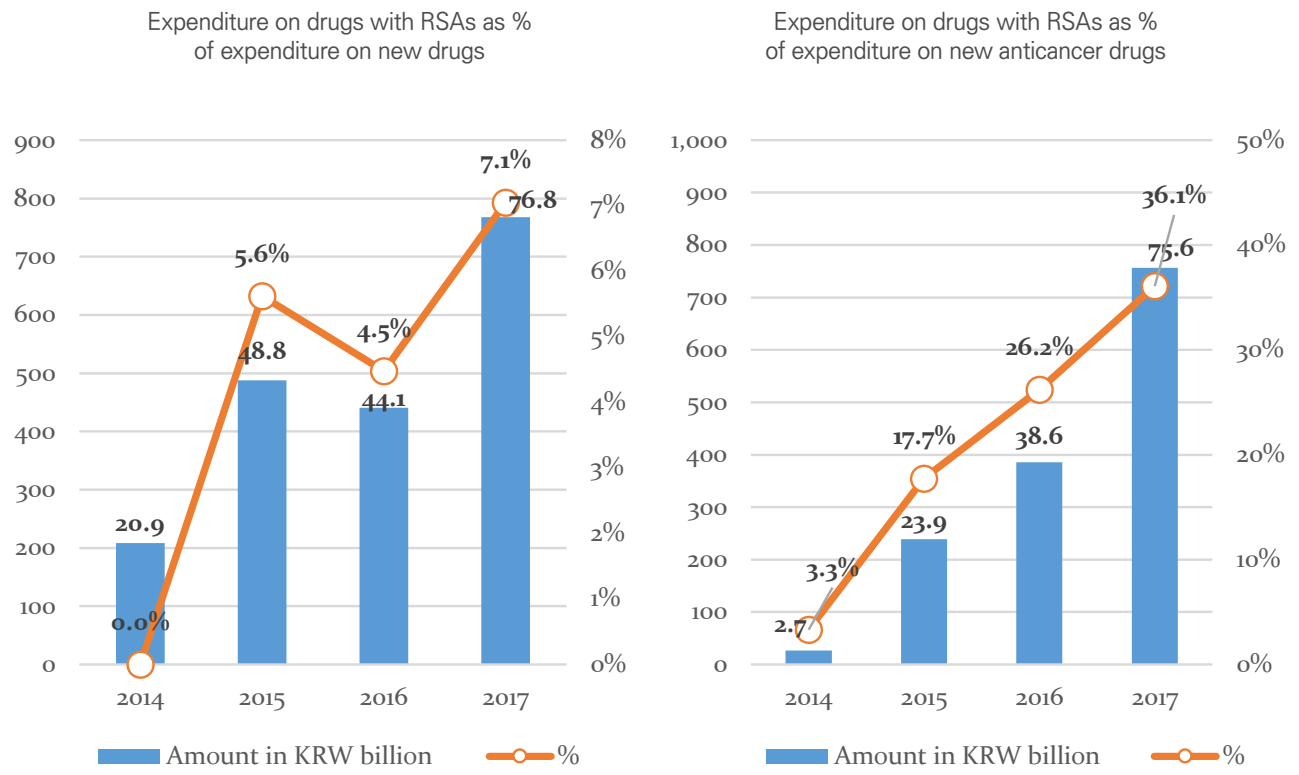
NHI expenditure on new pharmaceutical products increased from KRW392.5 billion in 2012 to KRW1089.8 billion in 2017 (Figure 5). NHI expenditure on new anticancer drugs increased in the same period from KRW20.2 billion to KRW209.6 billion. Anticancer drugs represented 5.1 percent of the expenditure on all new drugs in 2012. The proportion almost quadrupled to 19.2 percent in 2017.

[Figure 5] NHI expenditures on new drugs and new anticancer drugs



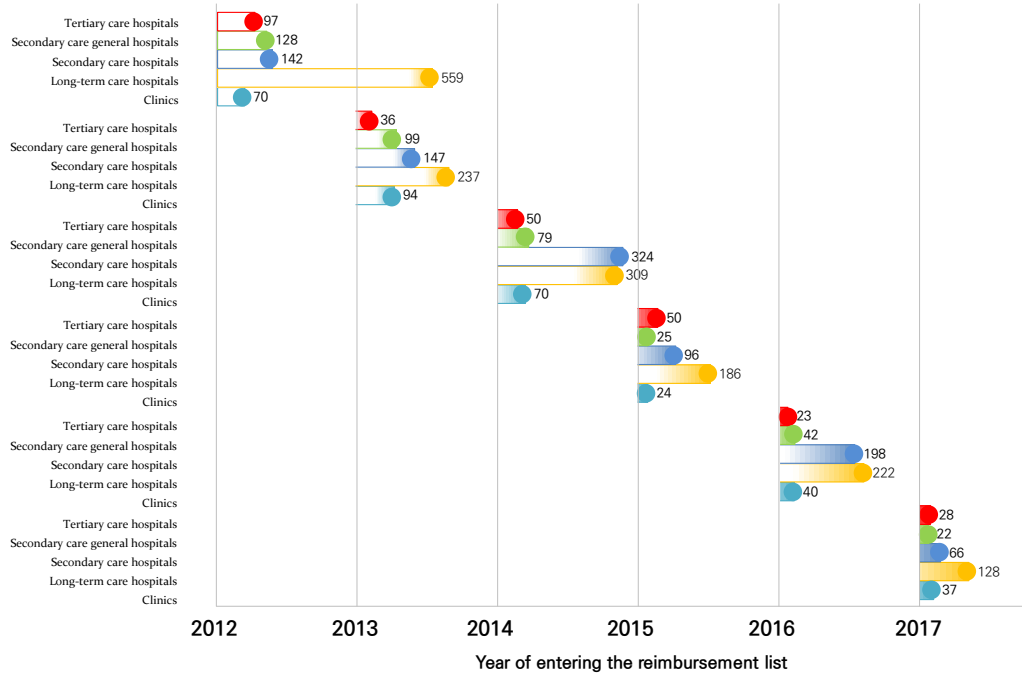
NHI's expenditure on new drugs with RSAs has been growing over the years, from KRW20.9 billion in 2014 to KRW76.8 billion in 2017, with its share in the expenditure on all new drugs rising from 2.9 percent to 7.1 percent (Figure 6). Drugs with RSAs as a share of the expenditure on all new anticancer drugs increased from 3.3 percent (KRW2.7 billion) in 2014 to 36.1 percent (KRW75.6 billion) in 2017 (Figure 6).

[Figure 6] Expenditure on drugs with RSAs as a share of expenditure on new drugs and as a share of expenditure on new anticancer drugs



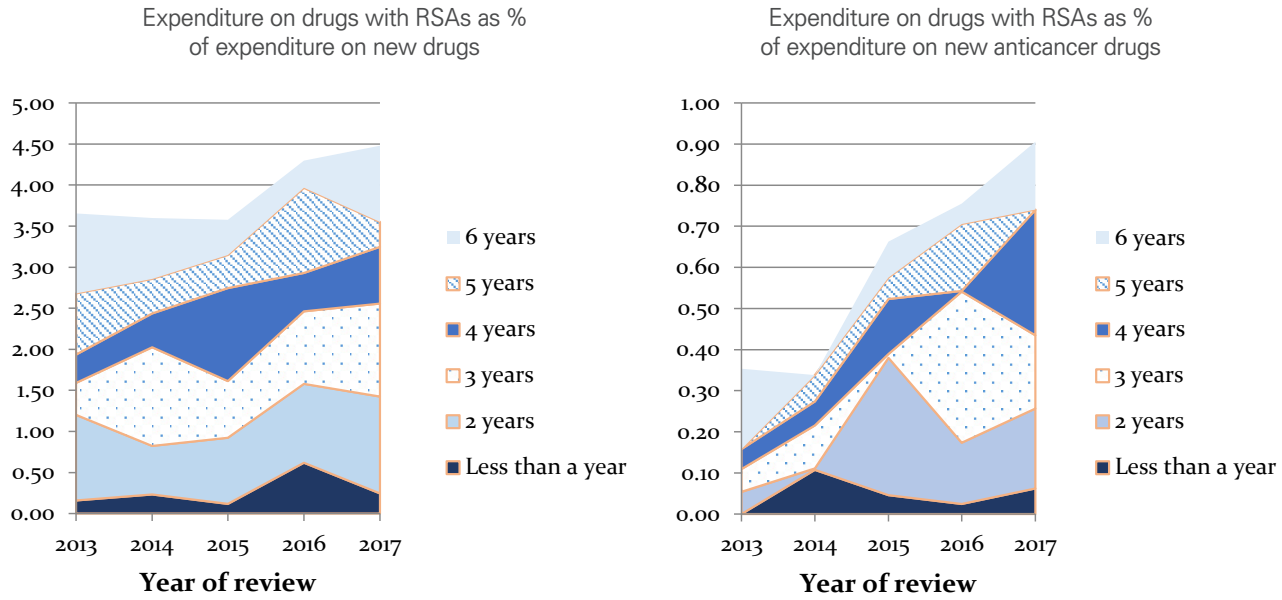
The time it takes for a new reimbursable drug to be approved for use at health care institutions has been getting shorter over the years. In 2017, the number of days it took for a new NHI-listed drug to reach tertiary care hospitals was 28, down from 97 five years earlier (Figure 7). During this period, the amount of time it takes for a new drug to go from the reimbursement list to hospital use has reduced for health care providers of all tiers.

[Figure 7] Average time taken for reimbursable drugs to be used at health care institutions, by year of inclusion in the reimbursement list



New listed drugs have been accounting for an increasing share of the NHI's pharmaceutical expenditure. Drugs within 6 years of being placed on the reimbursement list accounted for an increasing share of total expenditure on drugs, from 0.35 percent in 2013 to 0.91 percent in 2017 (Figure 8).

[Figure 8] Expenditure on drugs with RSAs as a share of expenditure on all new drugs andas a share of expenditure on new anticancer drugs, by review year and by the number of years on the reimbursement list



Concluding remarks

Anticancer drugs have increased both in number and as a share of total pharmaceutical expenditure. As anticancer drugs represent the most dynamic segment of the world's pharmaceutical development industry, they are expected to continue constituting an increasing percentage of new drugs making it to the market. The US FDA's priority review and the French HAS's ASMR suggest that more than half of new drugs lack, or are altogether without, added therapeutic benefit over existing treatments.

Many new drugs lack evidence of clinical efficacy and cost-effectiveness. Some of the drugs that have been approved for marketing in the US and EU countries—through accelerated approval or conditional marketing authorization—without conclusive clinical trials are being used in Korea. The proportion of such products is higher in anticancer medicines (46.8 percent) than in overall new drugs (15.4 percent). The process of having new drugs approved for marketing is becoming faster in Korea as it is elsewhere, with more and more new drugs being made available through such fast-track methods as accelerated approval and conditional marketing authorization. New drugs as a share of Korea's total pharmaceutical expenditure have been on the increase over recent years. An increasing number of drugs have been added to the reimbursement list through RSAs, accounting for a growing share of pharmaceutical expenditure. Against this background, there is a growing need for policy measures that ensure access to innovative new drugs while reducing uncertainties about their therapeutic values and keeping pharmaceutical expenditure sustainable.