TIME TO REIMBURSEMENT OF RSA DRUGS IN KOREA

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BACKGROUND

- **Risk-Sharing Agreement (RSA)** policy was implemented in Dec 2013 as the part of the Korean government's policy to expand NHIS (National health insurance service) coverage.
- Under this system, pharmaceutical companies share with regulatory bodies uncertainties about their new drugs in terms of impact on clinical outcomes and healthcare budgets. In exchange the companies receive accelerated patient access.
- There are four basic types of RSA: **1) Refund, 2) Expenditure cap, 3) Utilization cap per patient, 4) Coverage with evidence development (CED).** (Table 1)
- Although the RSA policy was implemented, some drugs may not be considered cost-effective. A Waiver for Cost Effectiveness Analysis (CEA) was introduced in Feb 2015 for eligible cancer or orphan drugs that are essential to clinical care but hard to prove cost effectiveness. Additionally these drugs have to be approved in at least three A7 countries*.

* A7: USA, UK, Germany, France, Italy, Switzerland, Japan

Table 1. Types of RSA scheme

Type	Detail
Refund	A designated rate of total insurance claim of the drugs (which is the gap between the listed price and the contracted price) is refunded by pharmaceutical companies to the NHIS
Expenditure cap	Refund to NHIS a designated rate of the exceeding amount which exceed the annual cap assigned in advance
Utilization cap per patient	The limit of use per patient is predetermined, and a designated rate of amount for exceeding the limit is refunded to the NHIS
Coverage with Evidence Development (CED)	During the limited period, pharmaceutical company conducts the clinical study, based on this results, NHIS decide whether to keep coverage

Objectives

- This study aimed to measure the time between regulatory approval and start of reimbursement for the RSA drugs between 2014 and 2020 in Korea. These times were then compared with times observed in the UK.

Methods

- Here we assessed drugs with RSA (n=42), from January 2014 until March 2020. Drugs were categorized by their RSA scheme, disease indication, and whether it had an accompanying CEA study.
- The mean time gaps between market authorization and reimbursement by national health insurance were evaluated (Figure 1).
- Approval data were obtained from the Korea Ministry of Food and Drug Safety (MFDS) and the related dates of reimbursement were collected from the official websites of the National Health Authority.
- We then compared Korea data to UK data. UK data was extracted from approval information hosted by the European Commission issued Marketing Authorization (EMA) and reimbursement data from National Institute for Health and Care Excellence (NICE) recommendations or from Cancer Drug Fund (CDF) reimbursement date.

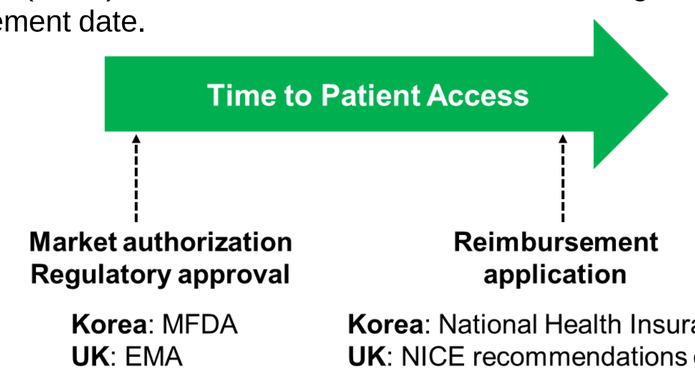

Figure 1. The process between regulatory approval and reimbursement application

Results

- Up until Jan 2020, 42 cancer or orphan drugs had participated in the RSA scheme. Among 42 drugs, 35.7% (n=15) of drugs were listed under RSA scheme in 2017. There were 21 expenditure cap-type, and 12 refund-type. There was only 1 case of health outcome-based RSA type (which is CED) and rest were financial-based RSA type. (Figure 2).

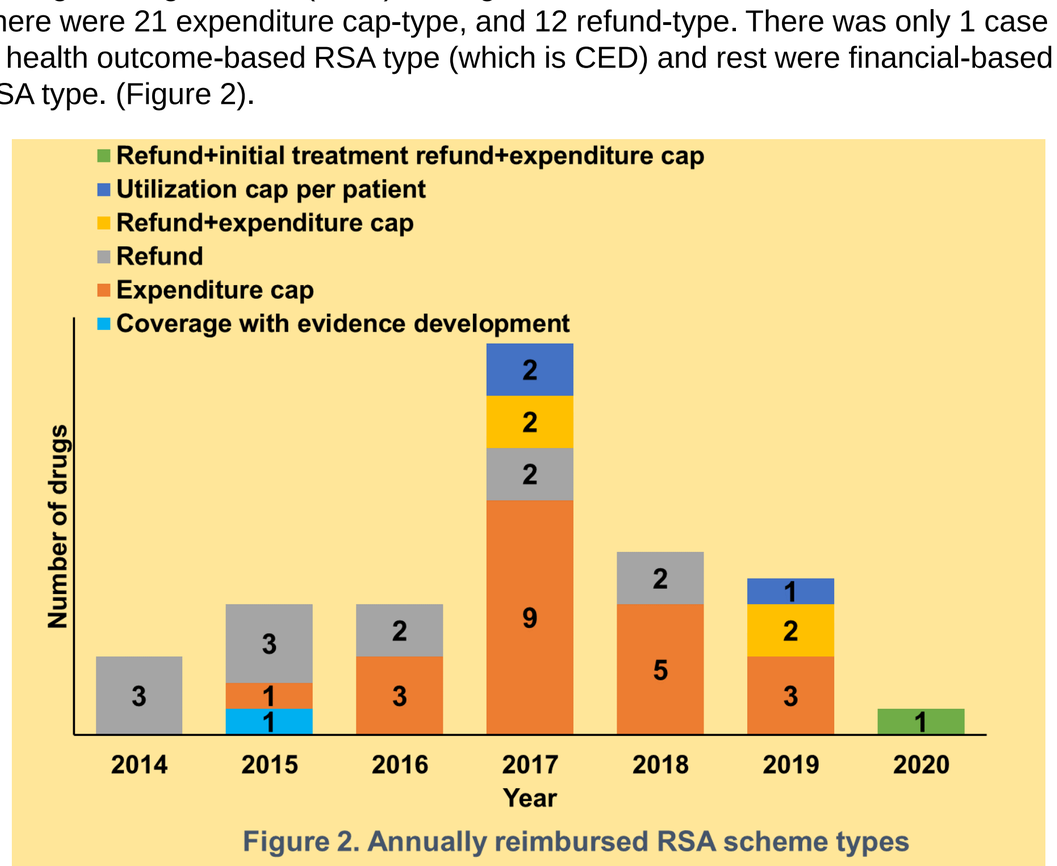

Figure 2. Annually reimbursed RSA scheme types

- The majority of RSA drugs that were reimbursed were for cancer and/or orphan disease indications except one (atopic dermatitis) in 2020. More than half (n=22) drugs were for cancers with an orphan disease status. Regarding inclusion of CEA, orphan drugs and cancer drug with orphan disease status tended to have a CEA waiver (89%, 68% respectively), on the other hand cancer drugs tend to accompanied a CEA study (70%; Figure 3).

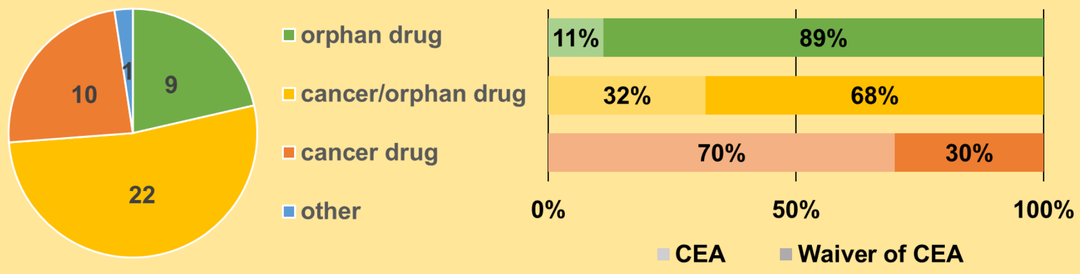

Figure 3. Disease types (Pie chart) and Waiver of CEA proportion (Bar chart) of Total 42 drugs

- Drugs with a CEA waiver were reimbursed more expeditiously compared to drugs with an accompanying CEA study. (27.8 months vs 30.8 months) (Figure 4).

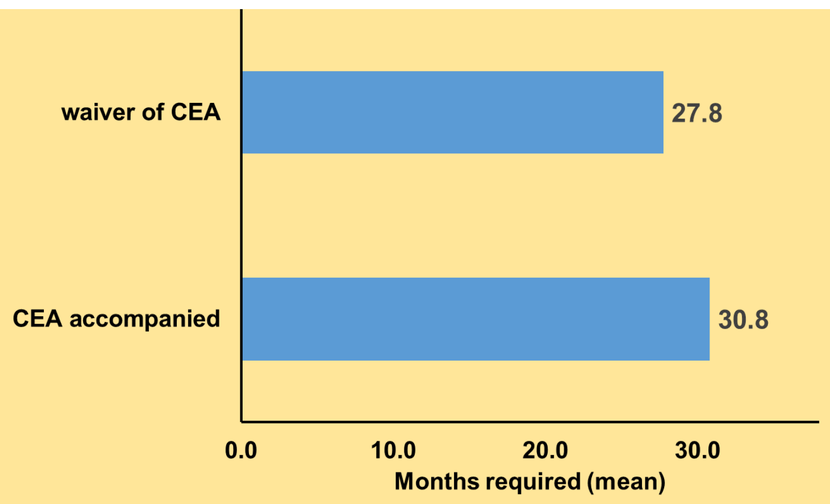

Figure 4. Average time (months) to patient access

- In particular, 26 drugs out of 42 drugs had a waiver of CEA analysis. More recent RSA drugs with such waivers tended to have a shorter lag time than drugs that performed CEA. The average listing period for a drug with a waiver was 26.7 months in 2017, 19.2 months in 2018 and 16.4 months in 2019. Meanwhile, the lag time for drugs with CEA was 29.7 months, 31.0 months, and 18.5 months, respectively (Table 2).

Table 2. Average time* to patient access categorized by with/without CEA

Year	Total (months required)		Waiver of CEA (months required)		CEA accompanied (months required)	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
2014	3	41.7 (± 18.5)	1	50.0	2	37.5 (± 21.5)
2015	5	45.6 (± 13.6)	3	48.5 (± 19.5)	2	39.0 (± 1.0)
2016	5	35.2 (± 31.8)	4	35.8 (± 35.6)	1	33.0
2017	15	27.3 (± 13.4)	8	25.1(± 14.7)	7	29.7(±11.2)
2018	7	22.6 (± 11.3)	5	19.2 (±12.4)	2	31.0 (± 5.0)
2019	6	16.3 (± 8.7)	5	16.4 (± 9.5)	1	16.0
2020**	1	21.0	0	N/A	1	21.0
Total	42	30.8 (±19.0)	24	20.1 (± 9.7)	15	29.5 (±10.0)

*Average time: Regulatory approval date to reimbursement application
**Only 1 drug is included in 2020

- Figure 5 compared time to patient access between Korea and UK from 2014 through 2020. RSA drugs in the UK tended to have a shorter lag time over that period. Nevertheless, time to patient access in Korea was continuously shortened.

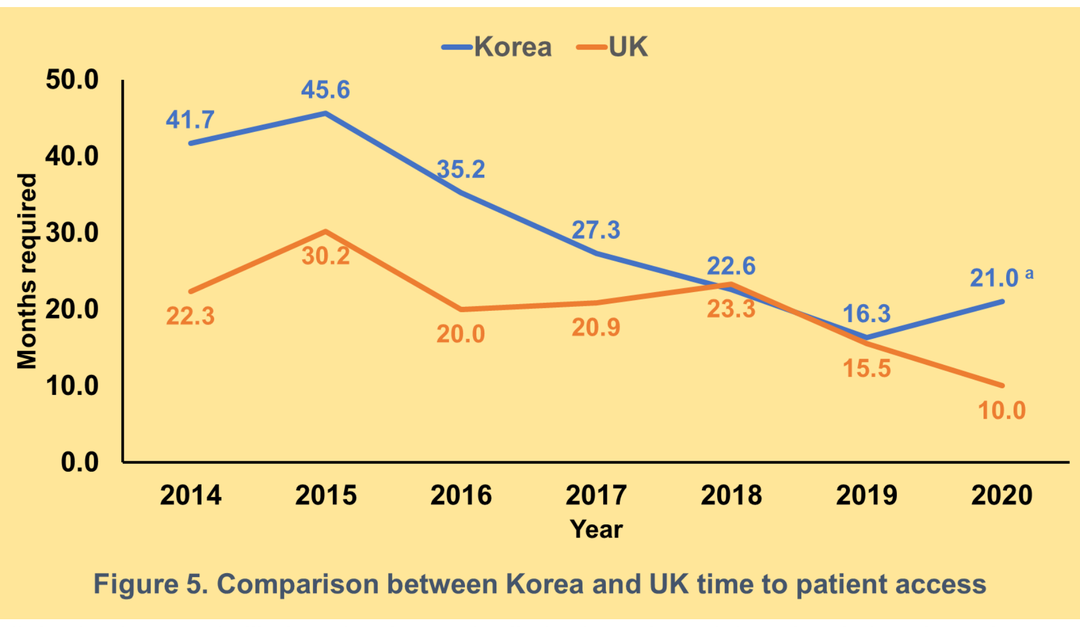

Figure 5. Comparison between Korea and UK time to patient access

[a] Slight rise in 2020 is likely to be due to the limited number of drug (n=1) data from that year

Discussion

- This study highlights the falling time to patient access for critical drugs since the introduction of the RSA system in Korea. RSA types in Korea are mostly financial-based, not-outcome based, except only CED (Coverage with evidence development) which is health outcome-based. Furthermore, drugs with a CEA waiver are reimbursed faster than those with a CEA.
- Since the UK uses additional drug access scheme such as Cancer Drug Fund (CDF) other than UK National health insurance, the time to patient access may seem shorter than access time in Korea.
- The Korean government is continuously implementing ways to accelerate patient access. They have made an official announcement to shorten the CEA review period and are planning to announce a revised RSA system in September 2020. Thus, we expect future government efforts will result in more expedited drug reimbursement in the future.

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