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Risk Sharing Agreements for Health Technology Assessment in the Brazilian National Health System, May 2019

## Risk Sharing Agreements in Korea

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- 1** Overall health care system in Korea
- 2** Drug P&R (pricing & reimbursement)
- 3** Risk Sharing Agreements

# Healthcare system in Korea

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# Korean Healthcare System

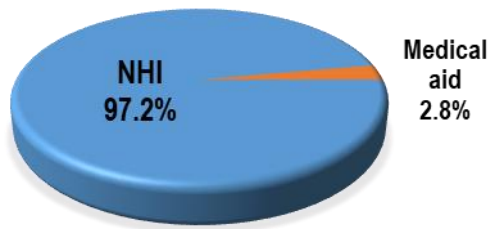
## Demography

- Total pop. 51,709,098
- Life expectancy :82.7yrs
- Aged society(14.9%)
- TFR ('18) : 0.977

## Economy

- 11<sup>th</sup> largest (\$1.655 trillion ),'18
- \$32,046 GPD per capita('18)

## Medical Security



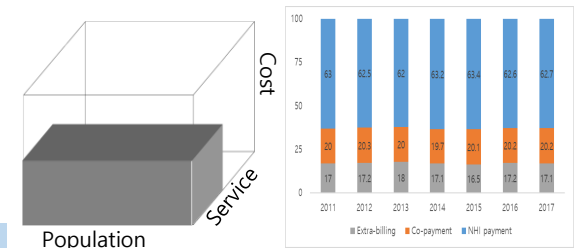
## 3rd Payer System



## History of NHI

- Implemented in 1977
- UHC for population achieved in 1989
- Unified single payer in 2000 (141 → 1)

## UHC



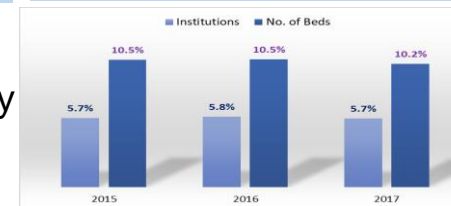
## Payment

- Basically FFS
- DRG for 7 diseases
- KDRG (pilot),2009

## Copayment

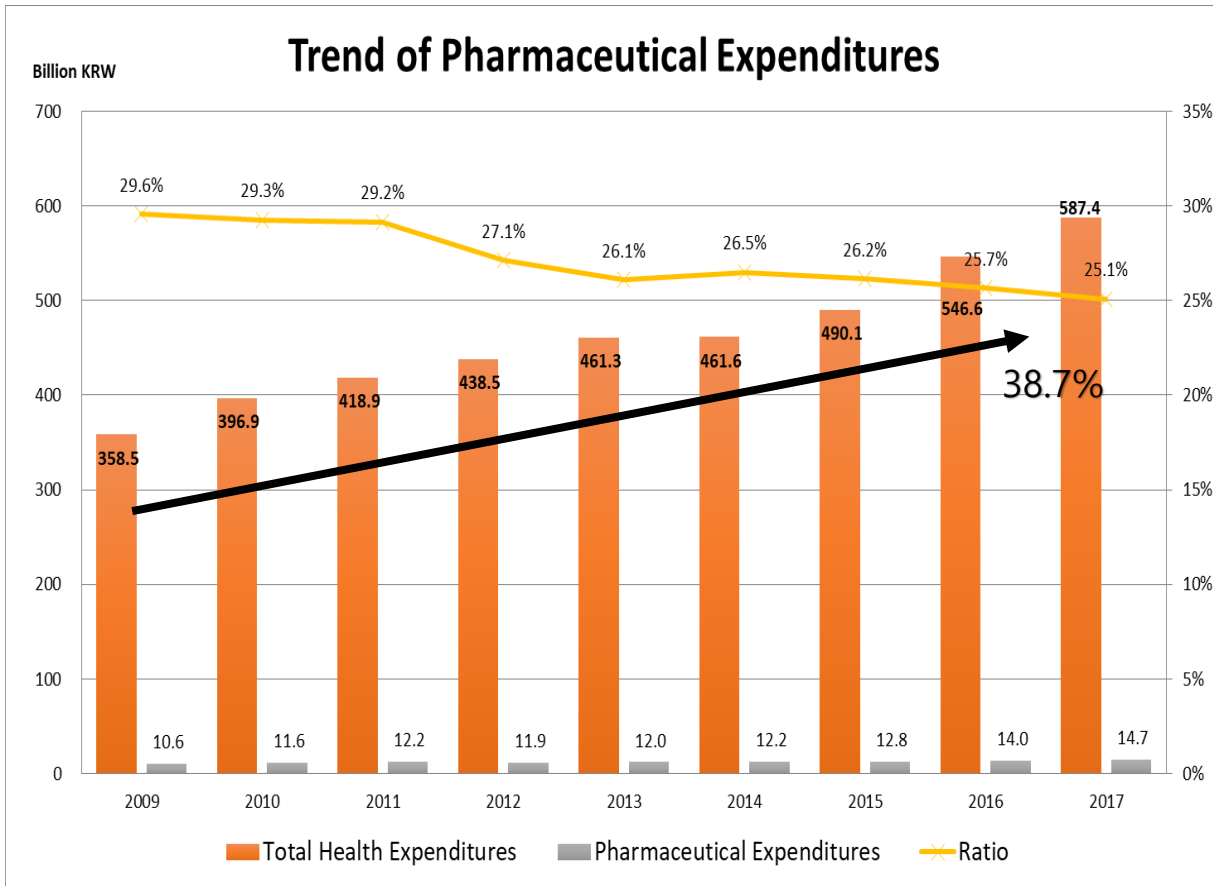
- 5% for cancer
- 30% for ambulatory
- 20% for inpatient

## Public institutions

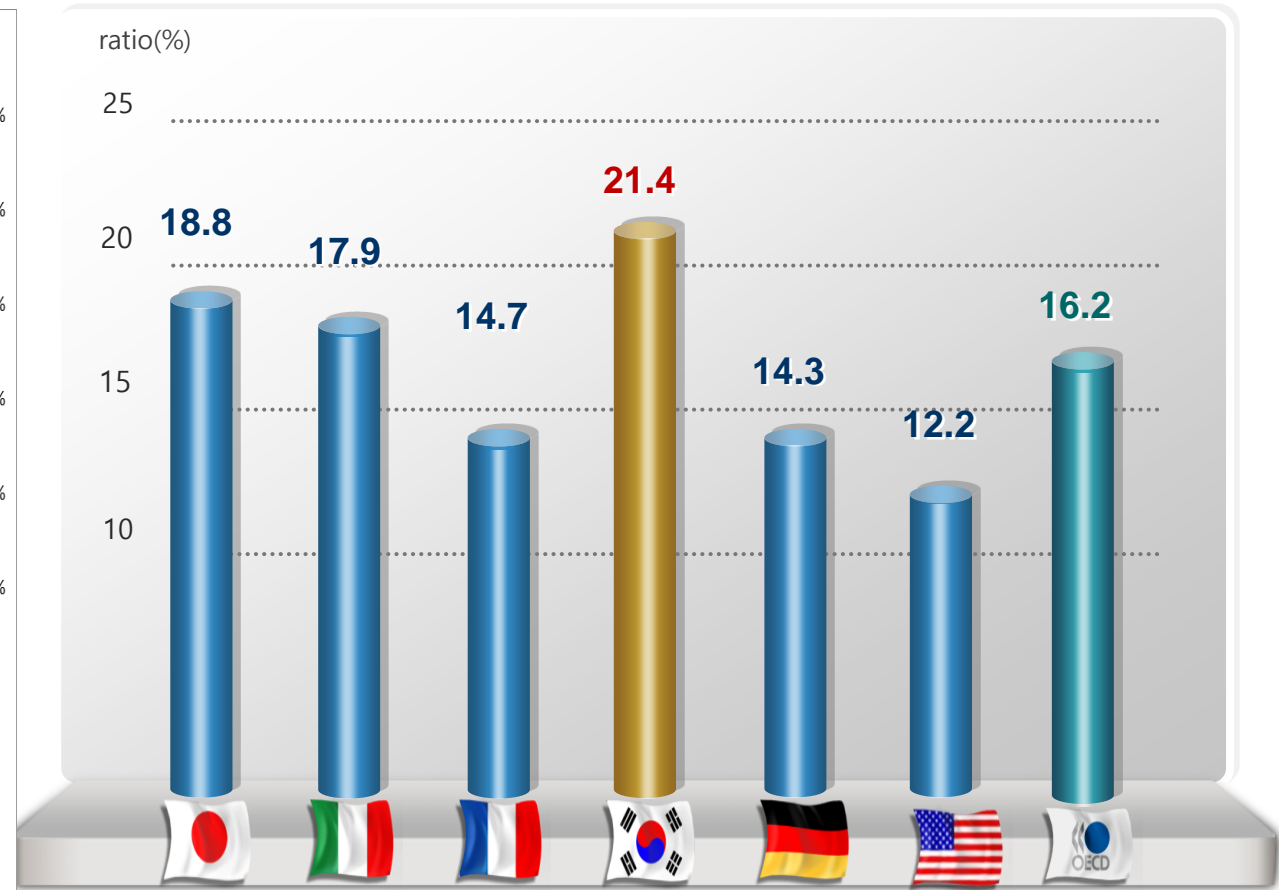


- BEP(Benefit enhancement plan)
  - "Listing all non-listed services" (4 major diseases since '12)
  - Expanded to all diseases under the Moon care

# Pharmaceutical Expenditures



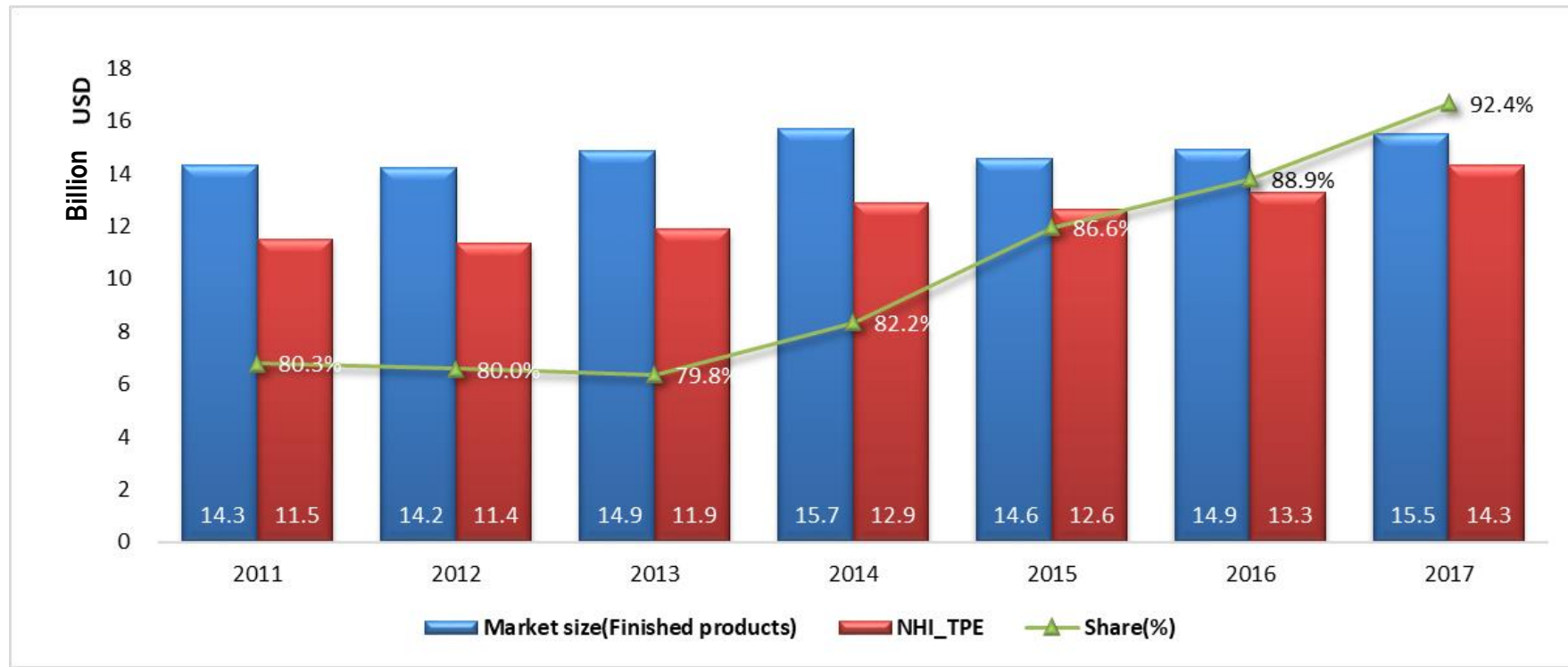
Source : NHIS Statistics (2019)



Source : OECD Health Data

# Importance of the NHI for Pharma. Industry

- TPE of the NHI : 92.4% of Market size(2017)

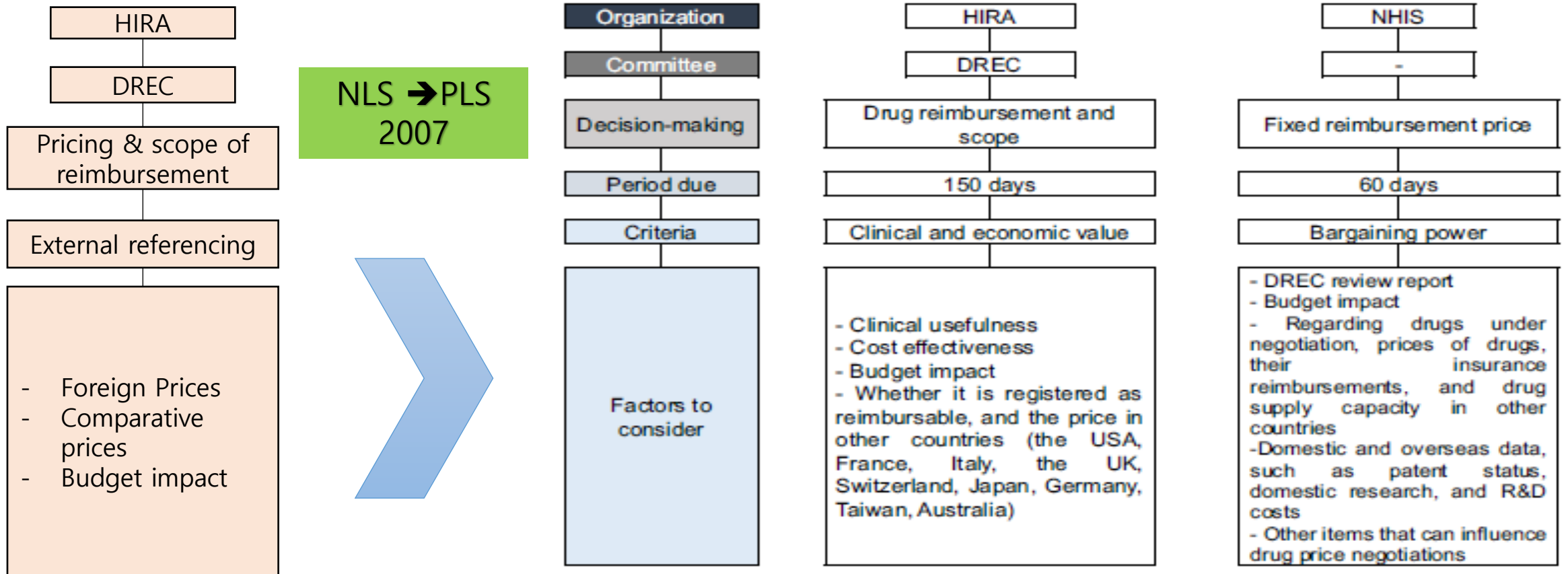


Source : MFDS & HIRA

# Drug P&R

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# Overall Drug P&R



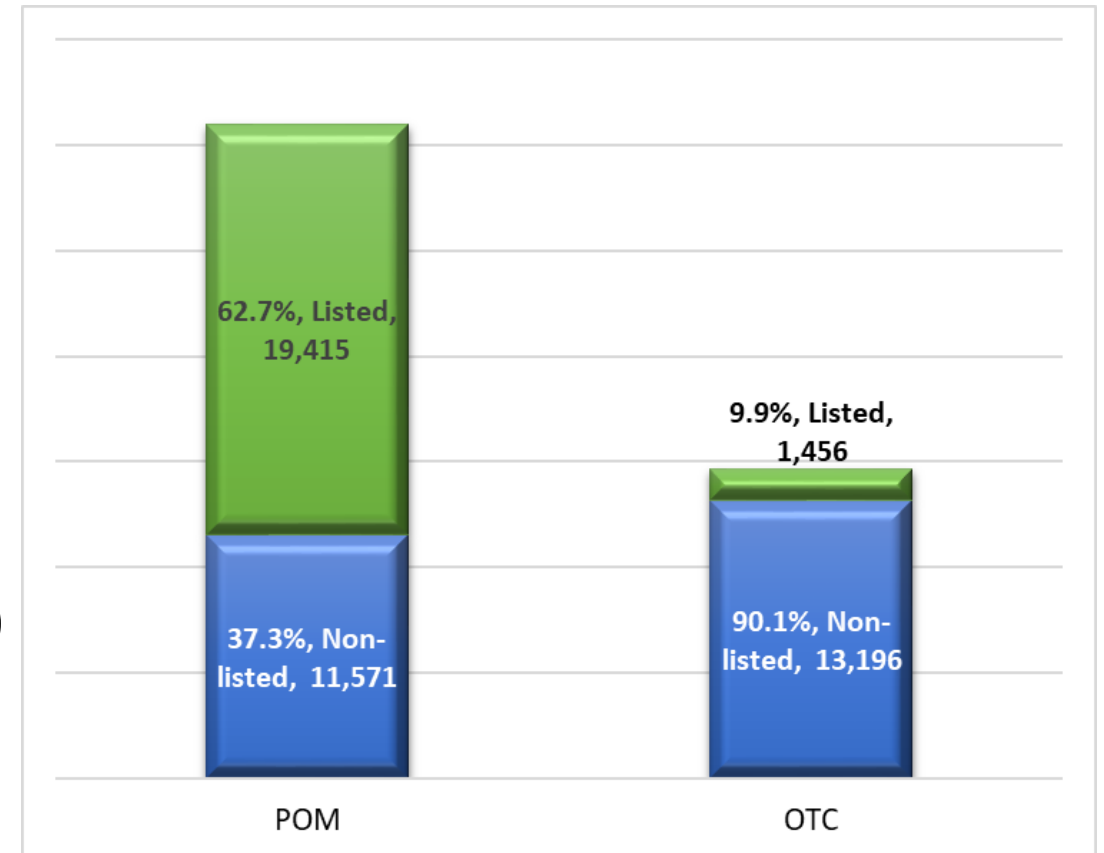
HIRA health insurance review and assessment service, NHIS national health insurance service, DREC drug reimbursement and evaluation committee.

Source : Kwon HY and Godman B, Drug pricing in South Korea, AHEHP 2017



# Drug Expenditure Rationalization Plan(DERP), 2007

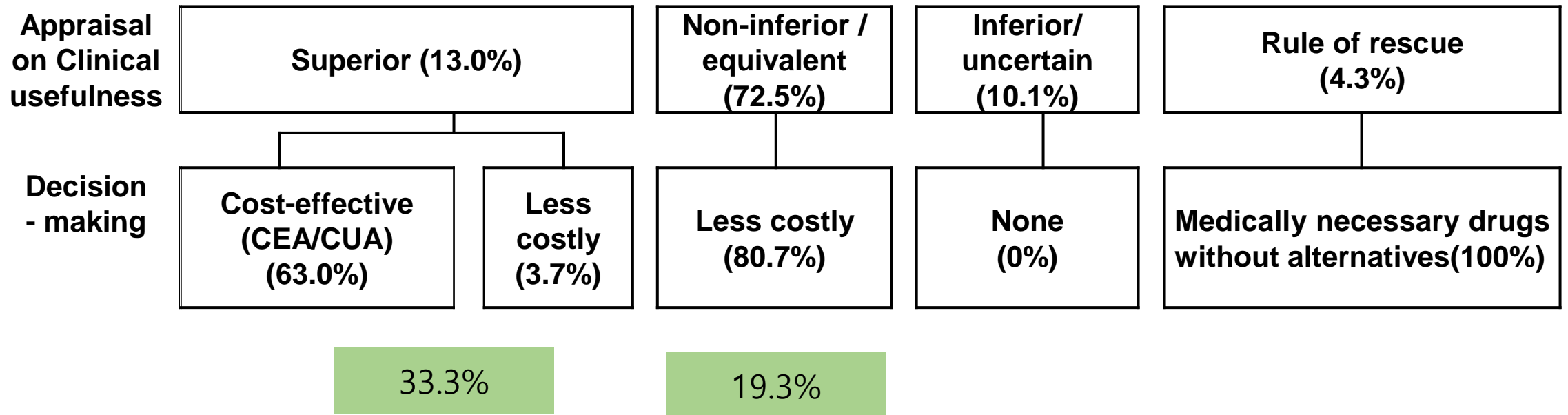
- To rationalize drug spending
- Two pillars
  - Positive listing
    - “Value for money“
    - 20,871 products (45.7% of all approved)
  - Price negotiation procedure
    - Bargaining power of the payer(NHIS)
    - Price-volume agreement



Source : [www.health.kr](http://www.health.kr) (as of May 02 2019)

# Decision on Reimbursement

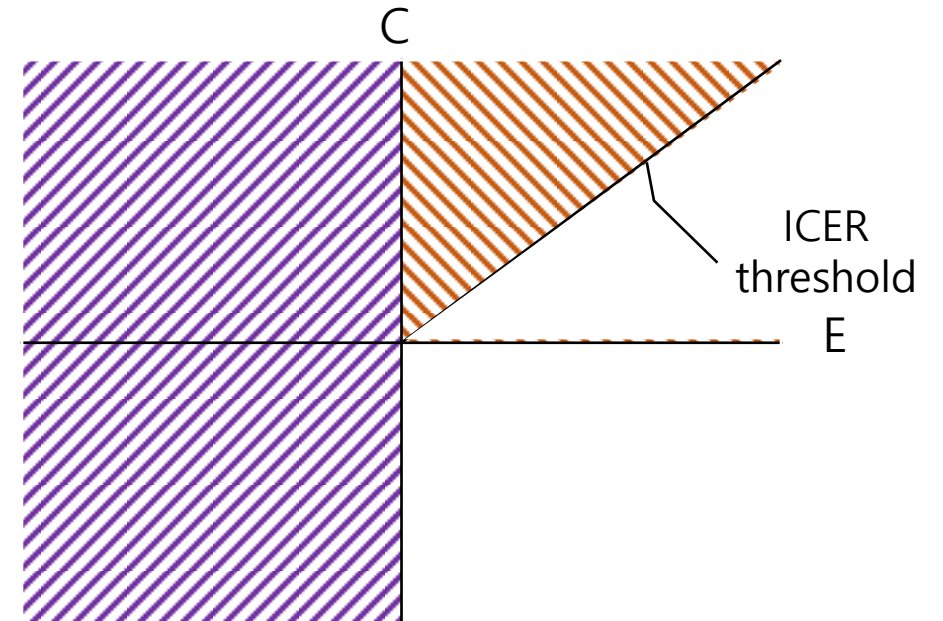
- Reimbursement rate : 71.5% during 2007 to 2012



Source : Yang BM et al(2012)

# Non-reimbursed medicines

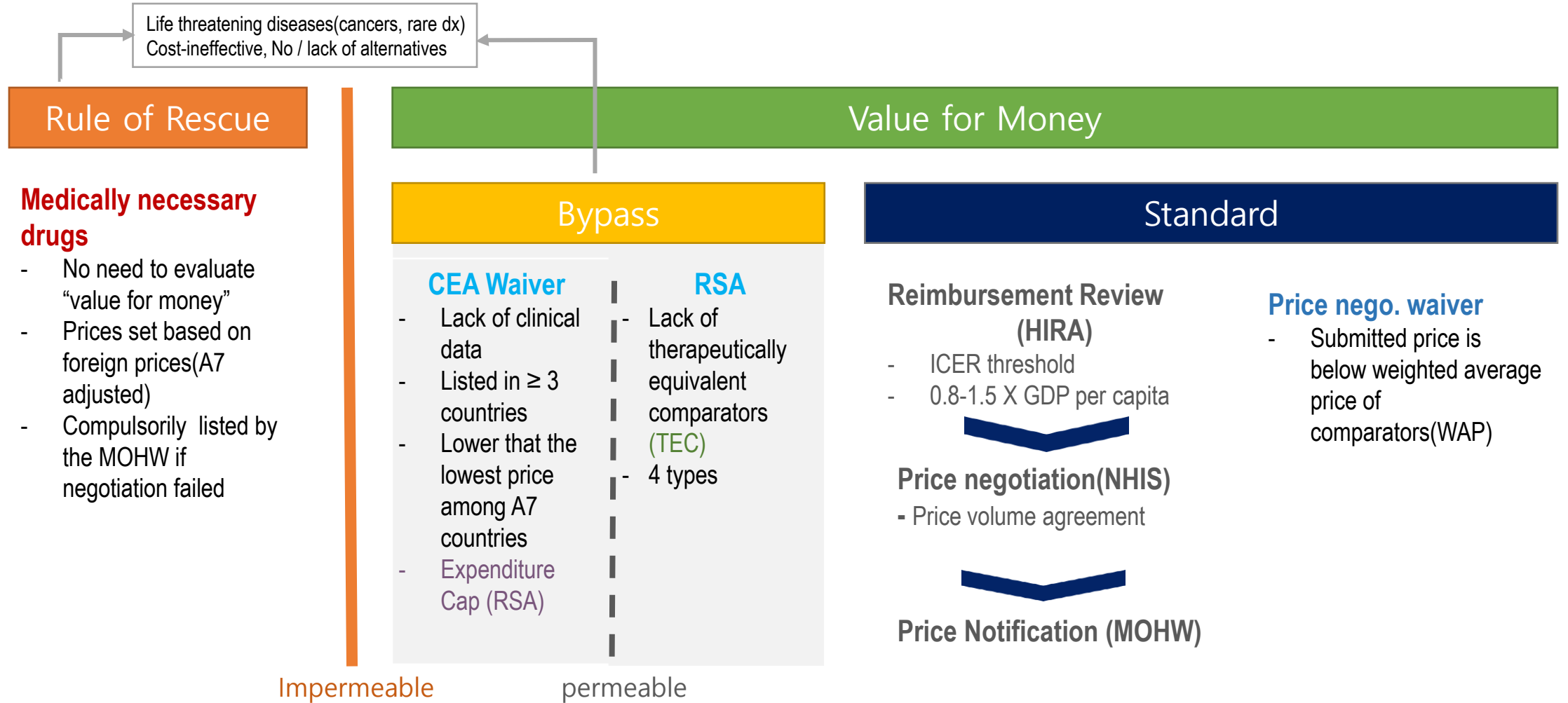
- Not sufficient evidence
  - ➔ uncertain effectiveness
- High cost medicines
  - ✓ ICER threshold
  - ✓ Cost-ineffective
- Breakdown of Price negotiation



➔ **Other mechanisms needed**

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# P&R Scheme



# Medically Necessary Medicines

- Eligibility (A ∩ B ∩ C ∩ D)

- A. In the absence of other treatments (including medications) that can be substituted
- B. When used for life-threatening diseases
- C. When used for a small number of patients such as rare diseases
- D. Demonstrated for clinically significant improvement, such as a substantially prolonged survival period
  - Or, the DREC are considered necessary for patient care

- Benefits

- To be listed by the authority of MOHW, despite the breakdown of the negotiation

Table 1. Drugs evaluated by HIRA in South Korea.

Brand Name	Active Substance	Indication	Evaluation Year
Cystadane	Betaine anhydrous	Homocystinuria	2007
Sprycel	Dasatinib	Leukemia	2007
Elaprase	Idursulfase	Mucopolysaccharidosis type II	2008
Naglazyme	Galsulfase	Mucopolysaccharidosis type VI	2008
Myozyme	Alglucosidase alpha	Pompe disease	2008
Zavesca	Miglustat	Gaucher's disease	2009
Inovelon	Rufinamide	Lennox-Gastaut syndrome	2010
Remodulin	Treprostinil	Pulmonary hypertension	2010
Soliris	Eculizumab	Paroxysmal nocturnal hemoglobinuria	2011
Carbaglu	Carglumic acid	Hyperammonemia	2014

Source : Yoo et al, 2019

# CEA waiver

## ■ Eligibility (A ∩ B ∩ C)

### A. Drugs for rare diseases or cancers

- No other treatment that can be substituted
- No therapeutically equivalent alternatives (medications or treatments) but for life-threatening diseases

### B. One of following medicines

- Drugs approved based on clinical data without control group
- Drugs approved based on Phase II clinical data but no supplementary document of Phase III clinical data
- Difficult to produce evidence due to small number of patients

### C. Already listed in more than 3 countries among GB, US, FR, DE, CH, IT and JP.

\* Expenditure cap should be applied

Table 4. Drugs with waiver policy of cost-effectiveness analysis requirement in South Korea.

Product	Active Ingredient	Indication	Reimbursed Year	Risk-Sharing Agreement Type
Caprelsa	Vandetanib	Thyroid gland cancer	2015	Expenditure cap
Adcetris	Brentuximab vedotin	Hodgkin's lymphoma	2016	Not applied
Imbruvica	Ibrutinib	Mantle cell lymphoma	2016	Not applied
Vimizim	Elosulfase alfa	Morquio syndrome	2016	Expenditure cap
Zykadia	Ceritinib	Non-small cell lung carcinoma	2016	Not applied
Blinicyto	Blinatumomab	Lymphocytic leukemia	2016	Not applied
Diterin	Sapropterin	Phenylketonuria	2017	Expenditure cap
Defitelio	Defibrotide	Hepatic veno-occlusive disease	2017	Expenditure cap
Zelboraf	Vemurafenib	Melanoma	2017	Expenditure cap
Lynparza	Olaparib	Ovarian cancer	2017	Expenditure cap
Meqsel	Trametinib	Melanoma	2017	Expenditure cap
Olita	Olmutinib	Non-small cell lung carcinoma	2017	Expenditure cap
Sylvant	Siltuximab	Castleman's disease	2018	Expenditure cap
Lartruvo	Olaratumab	Soft tissue tumors and sarcomas	2018	Expenditure cap
Iclusig	Ponatinib	Leukemia	2018	Expenditure cap

Source: HIRA, list of reimbursable drugs [32].

Source : Yoo et al, 2019

# RSA

- Eligibility (A or B)

- A. Drugs for rare diseases or cancers or other life threatening conditions that have no alternatives or no therapeutically equivalent medicines or treatments when used for life threatening diseases

- B. Other cases where the DREC recognizes the RSA application in consideration of disease severity, social impact, and other health care impacts

- Requirements

- Still, cost-effectiveness of the drugs eligible to the RSA should be evaluated (except Expenditure cap)

Table 2. Drugs listed with a risk-sharing agreement in South Korea (2014.1.–2018.6.).

Product (Active Substance)	Indication	Risk-Sharing Agreement Type	Cost Effectiveness Analysis (CEA)
Eboltra (clofarabine)	Acute lymphoblastic leukemia	Coverage with evidence development	X
Erbitux (cetuximab)	Colorectal cancer	Refund	O
Revlimid (lenalidomide)	Multiple myeloma	Refund	X
Xtandi (enzalutamide)	Prostate cancer	Refund	O
Xalkori (crizotinib)	Non-small cell lung carcinoma	Refund	O
Pirespa (pirfenidone)	Idiopathic pulmonary fibrosis	Refund	O
Soliris (eculizumab)	Paroxysmal nocturnal hemoglobinuria	Refund	X (essential drug)
Caprelsa (vandetinib)	Thyroid gland cancer	Expenditure cap	X (waiver of CEA)
Naglazyme (galsulfase)	Mucopolysaccharidosis	Refund	X (essential drug)
Stivarga (regorafenib)	Gastrointestinal tumors	Refund	O
Vimizim (elosulfase alfa)	Morquio syndrome	Expenditure cap	X (waiver of CEA)
Diterin (sapropterin)	Phenylketonuria	Expenditure cap	X (waiver of CEA)
Pomalyst (pomalidomide)	Multiple myeloma	Refund	O
Defitelio (defibrotide)	Hepatic veno-occlusive disease	Expenditure cap	X (waiver of CEA)
Perjeta (pertuzumab)	Breast cancer	Utilization cap per patient	O
Zelboraf (vemurafenib)	Melanoma	Expenditure cap	X (waiver of CEA)
Kadcyla (trastuzumab emtansine)	Breast cancer	Utilization cap per patient	O
Keytruda (pembrolizumab)	Non-small cell lung carcinoma	Refund/ Expenditure cap	O
Opdivo (nivolumab)	Non-small cell lung carcinoma	Refund/ Expenditure cap	O
Lynparza (olaparib)	Ovarian cancer	Expenditure cap	X (waiver of CEA)
Meqsel (trametinib)	Melanoma	Expenditure cap	X (waiver of CEA)
Ibrance (palbociclib)	Breast cancer	Refund	O
Olita (olmutinib)	Non-small cell lung carcinoma	Expenditure cap	X (waiver of CEA)
Tagrisso (osimertinib)	Non-small cell lung carcinoma	Refund	O
Rafinlar (dabrafenib)	Melanoma	Expenditure cap	X (waiver of CEA)
Alecensa (alectinib hydrochloride)	Non-small cell lung carcinoma	Expenditure cap	X (waiver of CEA)
Tecentriq (atezolizumab)	Non-small cell lung carcinoma	Expenditure cap	X (waiver of CEA)
Sylvant (siltuximab)	Castleman's disease	Expenditure cap	X (waiver of CEA)
Kyprolis (carfilzomib)	Multiple myeloma	Refund	O
Lartruvo (olaratumab)	Soft tissue tumors and sarcomas	Expenditure cap	X (waiver of CEA)
Iclusig (ponatinib)	Leukemia	Expenditure cap	X (waiver of CEA)
Imbruvica (ibrutinib)	Mantle cell lymphoma	Expenditure cap	X (waiver of CEA)
Cyramza (ramucirumab)	Gastric cancer	Refund	O

(Note) Of the 33 total medications, two (Pirespa and Revlimid) have been terminated due to generic drug registration.

Source : Yoo et al, 2019

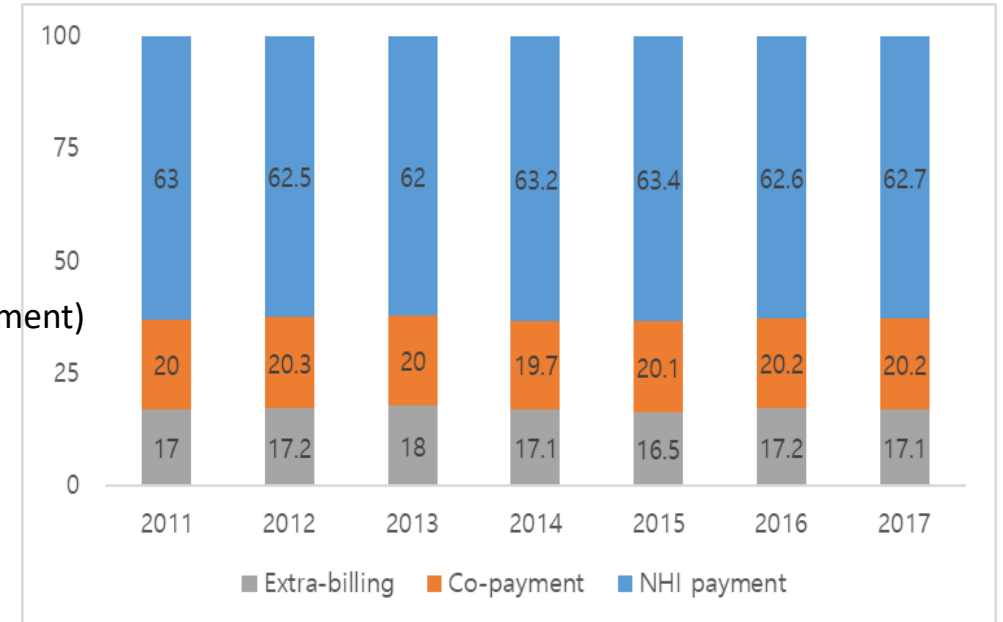
# Risk Sharing Agreements

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# Backgrounds

- Positive List System
- Balance billing
  - inveterate prescribing behavior
- Benefit Enhancement Plan (continued from the former government)
  - 4 major dx → all dx
  - The Moon Care : Listing all non-listed services
- Policy directions in Economy to foster pharmaceutical industry for economic growth



# 4 types of RSA

## ■ 33 drugs(2013.12~2018.6)

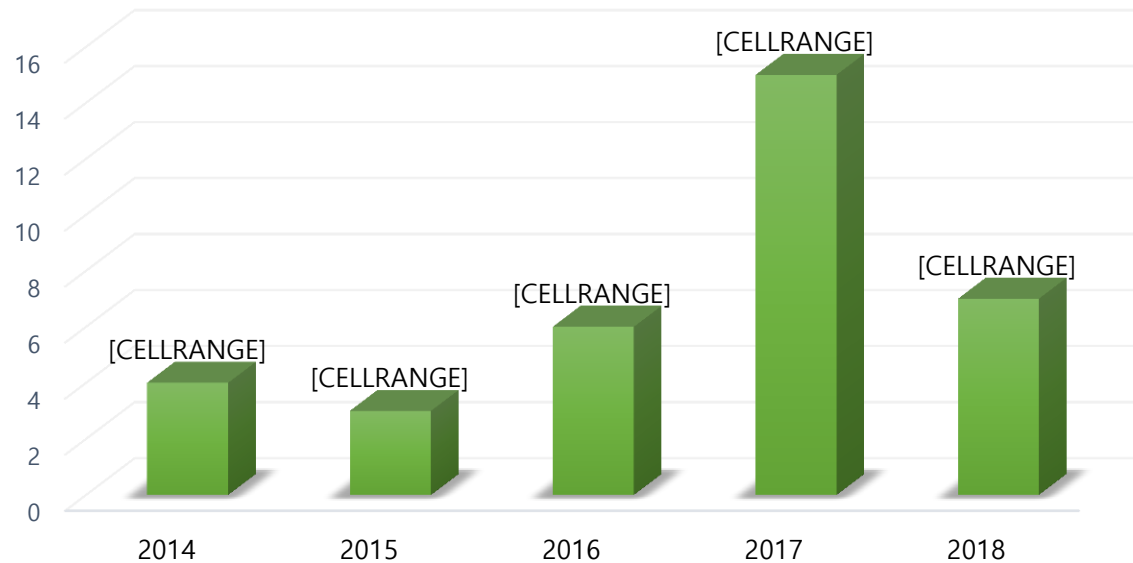
Types	Cancer drug	Cancer + orphan drug	Orphan drug	Total(%)
1. Expenditure cap	2	10	3	15(45.5)
2. Refund	6	3	3	12(36.4)
3. Utilization cap per patient	2	1	-	3(9.1)
Refund+Expenditure cap	2	-	-	2(6.1)
4. Coverage with additional evidence	-	1	-	1(3.0)
Total	12	15	6	33(100)



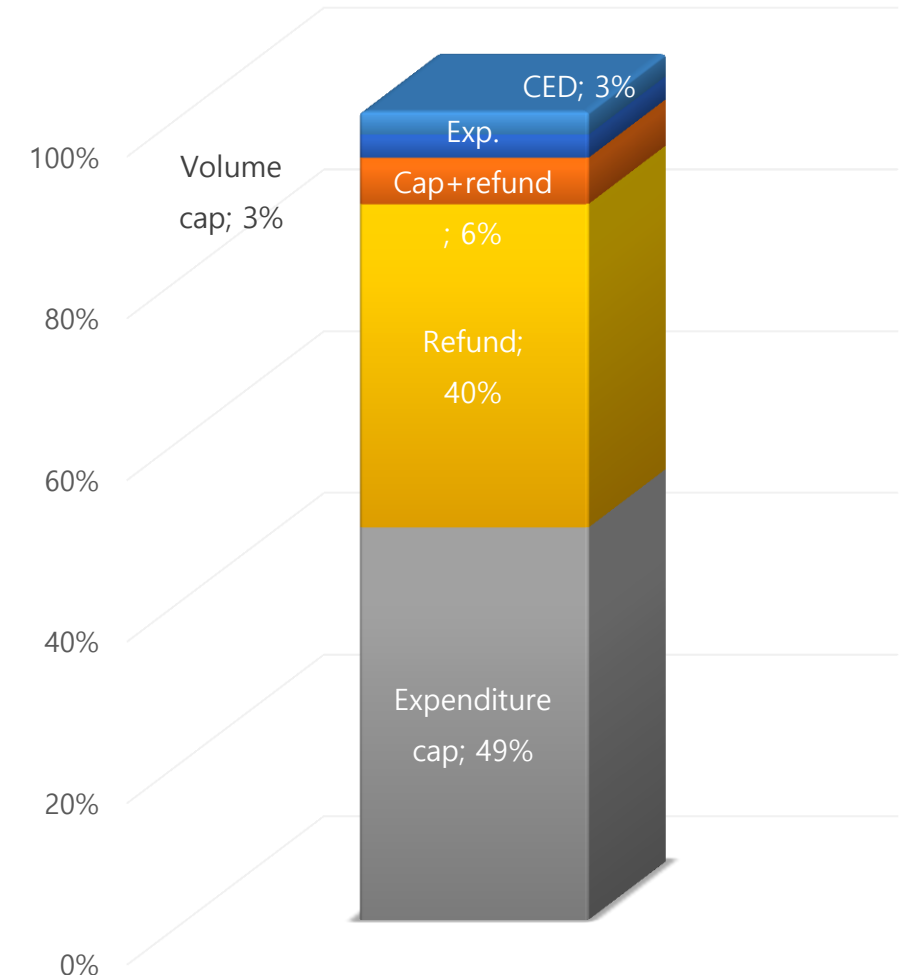
Source : Yoo et al, 2019

# So far.....

- 35 drugs contracted with RSA



- 3 drugs (Revlimide, Pirespa, Evoltra) were terminated.
- Pirespa : Real price was 40.8% lower than the optical price



# Finance-based

- Expenditure cap

- Refund  $E_{\Delta}$  to the NHI

- $E_{\Delta} = E_{actual} - E_{capped} = P * Q - E_{capped}$ , if  $E_{actual} > E_{capped}$

- Refund

- Refund  $E_{\Delta}$  to the NHI

- $E_{\Delta} = (P_{fake} - P_{real}) * Q_{actual}$

- Utilization cap per patient(volume cap)

- Refund  $E_{\Delta}$  to the NHI

- $E_{\Delta} = P * (Q_{actual} - Q_{capped})$ , if  $Q_{actual} > Q_{capped}$

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# Performance-based

- Coverage with Evidence Development(CED)

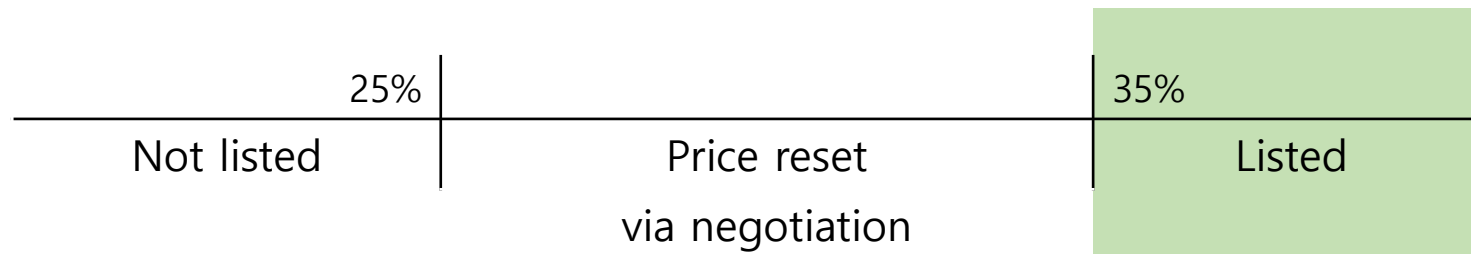
- Evoltra<sup>R</sup>(Clofarabine) 1mg/1ml

- Approved for treating relapsed or refractory acute lymphoblastic leukemia (ALL) in children after at least two other types of treatment have failed.
      - Not known if it extends life expectancy
      - Conditional approval requiring Phase III later
-

# Evoltra

- Study design by Subcommittee for RSA under the DREC, HIRA
  - Endpoint, observation period, Sample size, Methodology
  - Patient recruitment every 6 months to be reported to the committee

## Remission rate



# Lesson learned



- Improved access to medicines
  - 2.46 times(log odds) for Cancer drugs(Kim ES et al, 2016)

- Transparency in Pricing
- Patient copayment
- Administration costs
  - NHIS identifies and pays back to each patient(refund type)
- Impact was not evaluated yet

감사합니다.  
Thank you !

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