Korean HTA, Rethinking

University of Tokyo HTA Session

by

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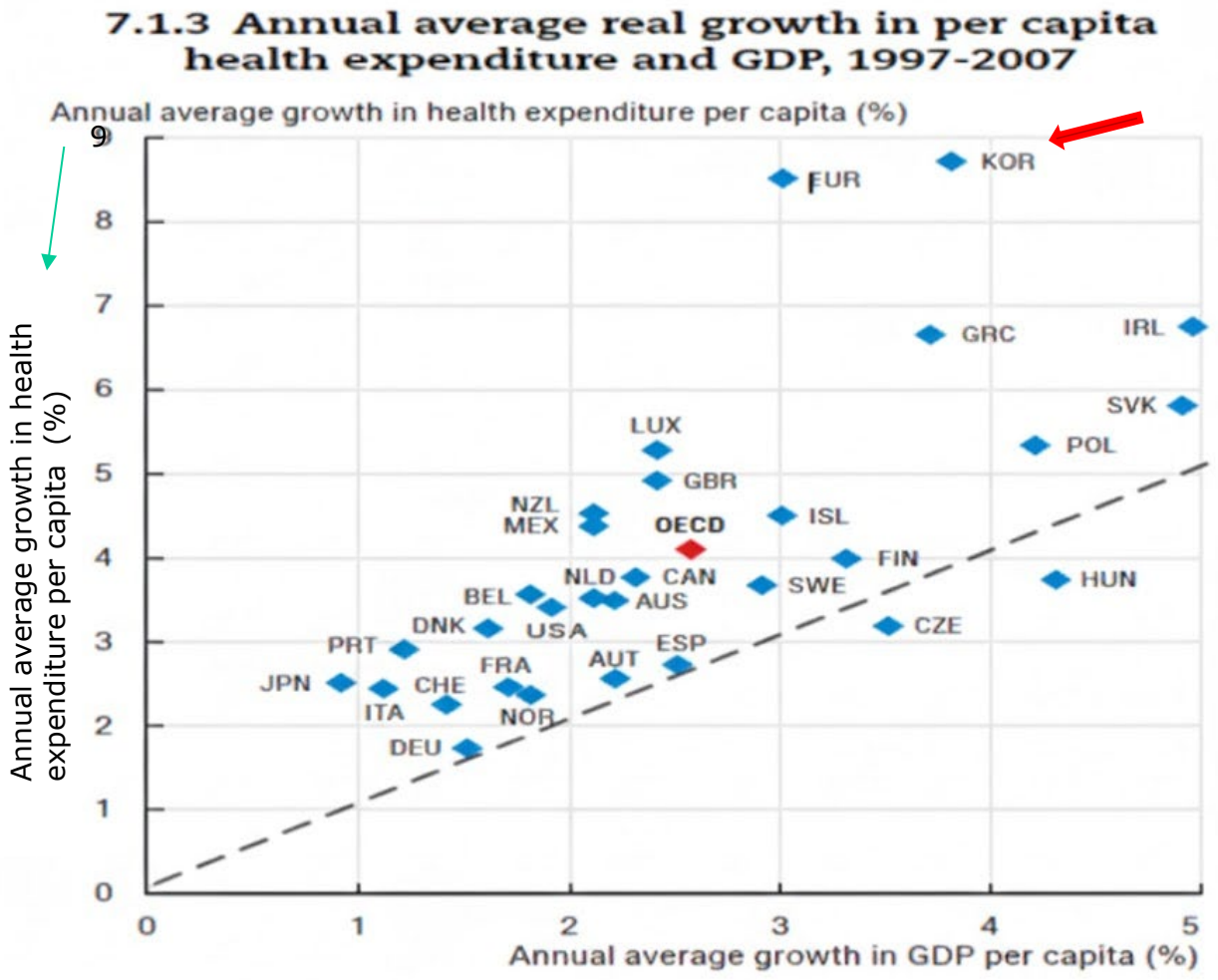
Korea introduced the PLS (Positive List System) in 2007

- Under PLS, PE (PharmacoEconomics) using HTA(health technology framework) introduced in 2007, as a key tool for value-based reimbursement decisions in South Korea
- Under PLS, NHI listed new drugs and their prices governed by NHIS (National Health Insurance Service), using PE HTA mechanism
- Why did we choose to go for Positive Listing System(PLS)?



OECD, Health Data, 2008

Background of Introducing Positive Listing System (PLS) in Korea, 2007

- High real growth in per capita health expenditure
- High drug expenditure annual growth rate, `98-`06
- Drug expenditure/NHE relatively high

	OECD average	Korea	US	France	Japan	Germany
Drug exp. annual growth rate ('98~'06, %)	5.9	12.3	8.5	5.7	3.6	5.5
Drug/NHE ('08, %)	17.44	23.9	11.9	16.4	20.1	15.1

Source: OECD Health Data, 2009/2010

- Korea's 'Rate of real per capita health expenditure growth' had been one of the highest globally

- Joined by very high annual growth rate of drug expenditure

- Rate of drug expenditure out of GDP far exceeded that of OECD average

- Korean NHI adopted policy of PE CEA (HTA) for new drugs

Why HTA?

- Underlying philosophy of HTA: utilitarianism - CE(cost-effectiveness)
- HTA looks for ‘value for money’ for medical technologies, including new drugs
- Before going into details of HTA and value for money, it is worth observing the ‘Overview of Korean Health Service Delivery System’

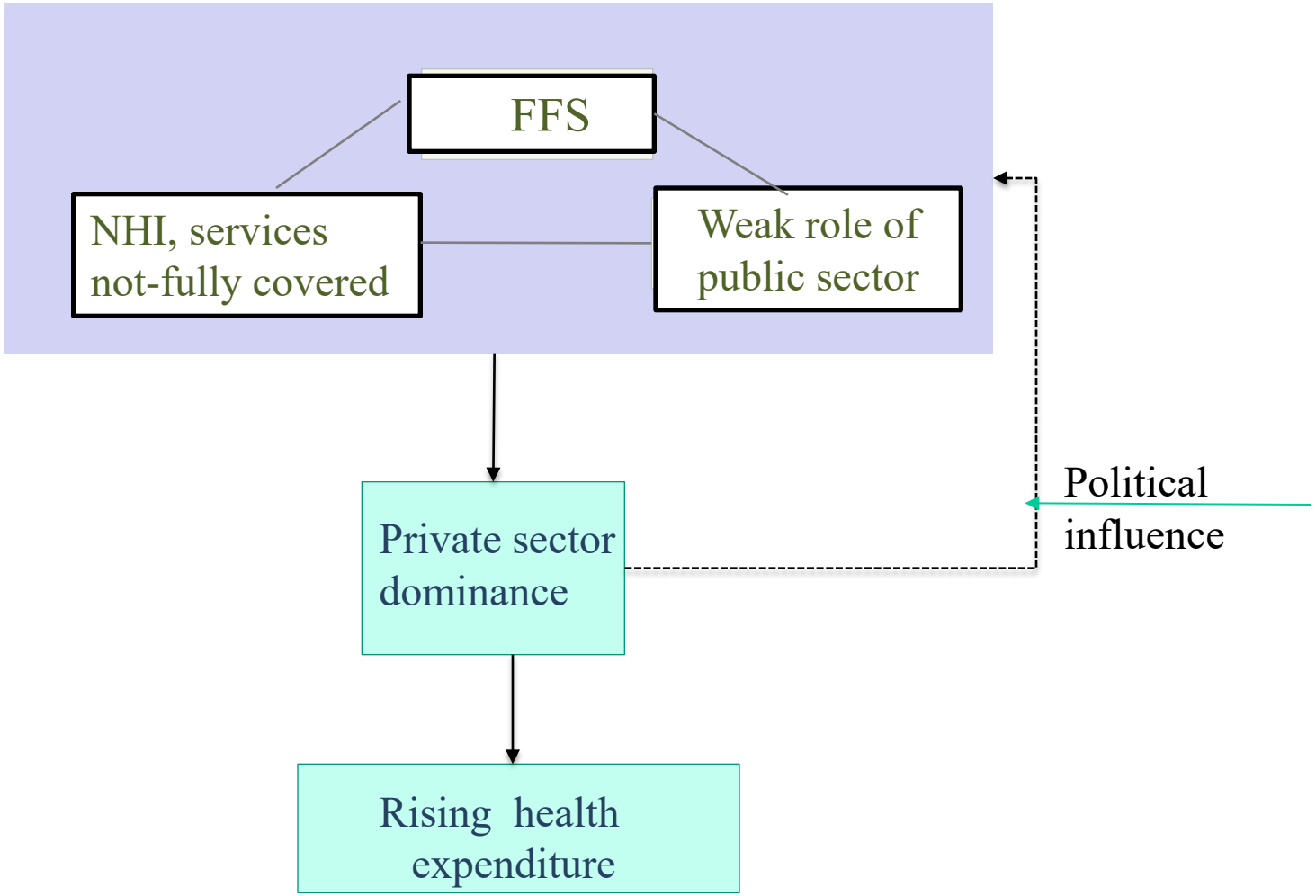
Overview of Korean Health Care Delivery

- Provider payment
  - Fee-for-service (FFS) with limited use of New-DRG (K-DRG + FFS) for inpatients.
  - FFS for all outpatients (patients at hospitals and local clinics)
- Privatized system
  - Private providers (profit-oriented) dominant – 94.7% of total providers (2023, KOSIS data)
  - Private hospital beds – 90.6% of total hospital beds (2023, KOSIS)
  - That means, a ‘fairly weak public sector’
- Service delivery
  - Large hospital sector and relatively small primary care network
  - More than 36% of outpatient treatments covered by hospitals (2023)

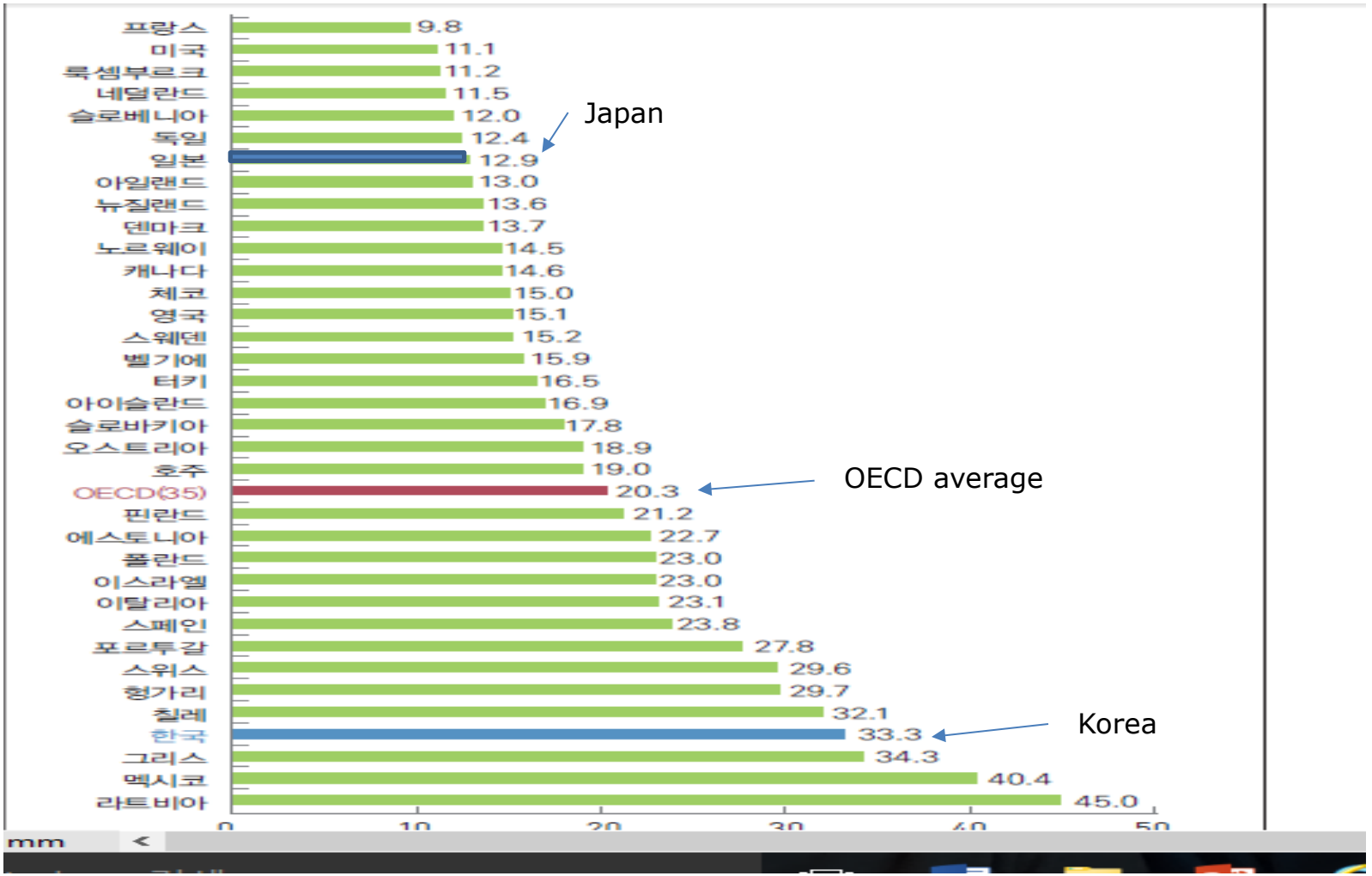
Overview - continued

- NHI
  - Single payer administration, NHIS (National Health Insurance Service)
  - Scaled insurance premium, based upon financial ability
  - For NHI sustainability, its contribution rates have been raised every year. ex) 2002, 3.63%; 2012, 5.80%; 2021, 6.86%; 2023, 7.09%
- Government financial support, a small fraction of total NHI outlay, 11.5% (2024)
- Uniform benefit package (covering **basic** cares, tests, drugs, and technologies included) for all beneficiaries
- But limited service coverage
  - Expensive technologies (CT, MRI, some tests) partially covered
  - Expensive new drugs not fully covered
  - Eventually, people end up with paying a good portion of total costs as OOP (out-of-pocket), 35.1% (2023, KOSIS)

Quick Overview of Korean Health Care Delivery



Out of Pocket Payment/Total Health Expenditure

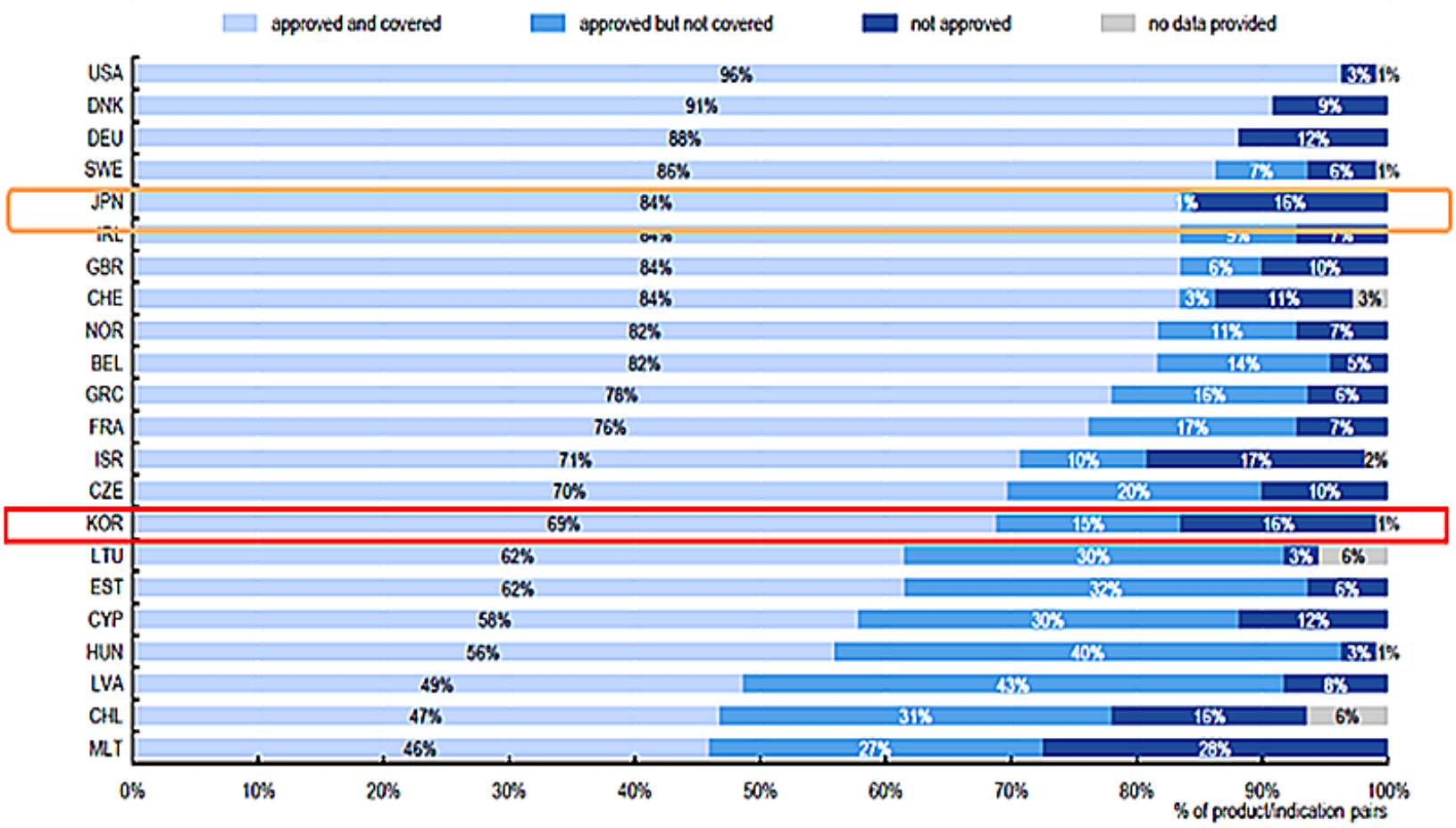


OECD Health Statistics, 2018

What has happened in the arena of pharmaceutical sector, after the introduction of PLS(Positive Listing System)?

Figure 3.2. Percentage of sample product/indication pairs by approval and coverage status across OECD/EU countries

A: Based on total sample of 109 product/indication pairs : ESMO(European Society for Medical Oncology) survey



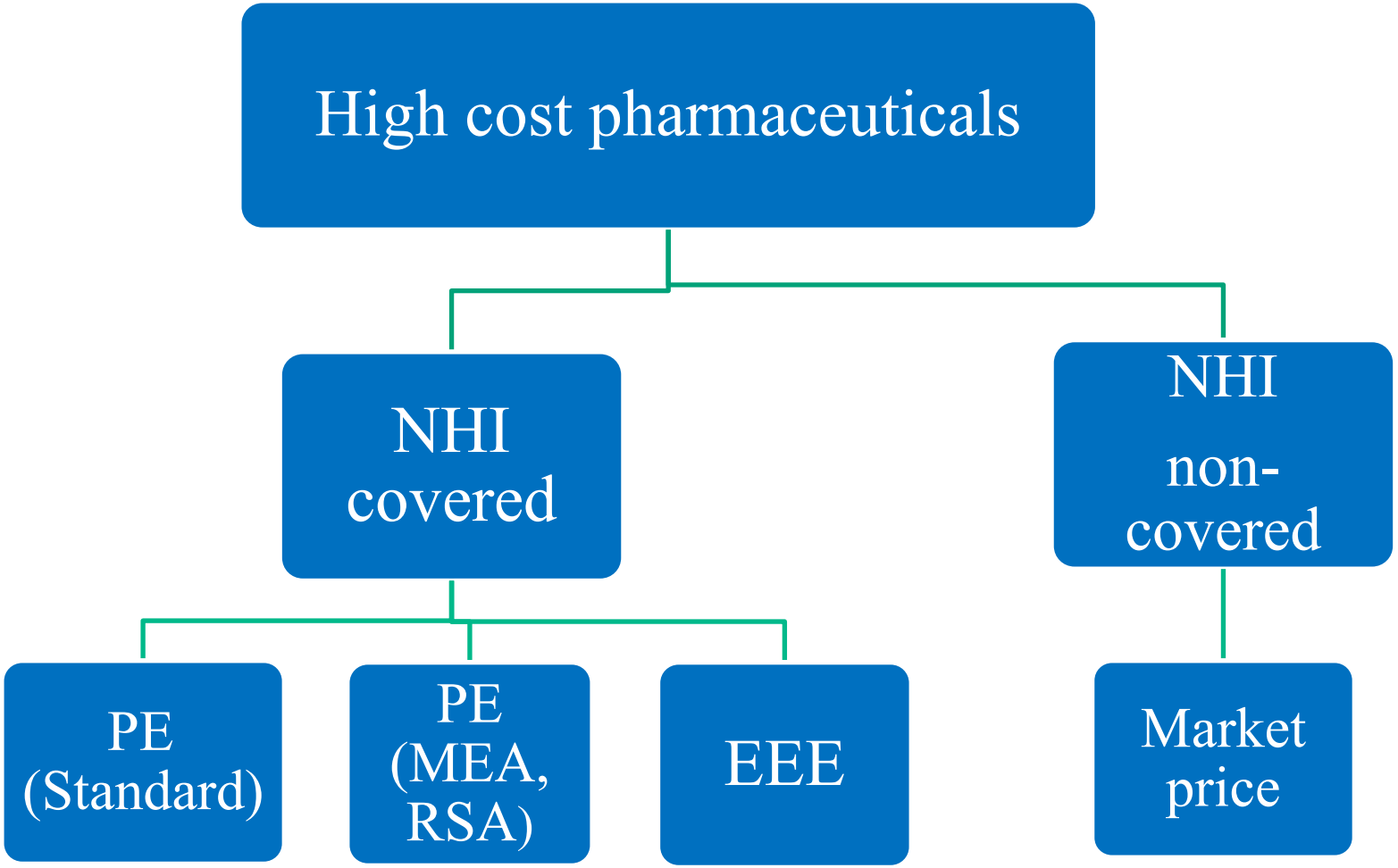
- Source: OECD (2020), Challenges in access to oncology medicines: Policies and practices across the OECD and the EU, OECD Health Working Papers No.123

Drug Coverage

(sample selected oncology drugs, EU survey, OECD, 2020)

	Approved & covered	Approved, but not covered	Not approved
Korea	69%	15%	16%
Japan	84%	1%	16%

Note: There are three categories of 'approved & covered' drugs in Korea,
(i) standard PE drug
(ii) MEA PE drug
(iii) PE Exempt (EEE) drug



note: In the case of NHI non-covered drugs, market prices are being charged directly toward patients

Classification of High Cost Pharmaceuticals, by K-NHI Coverage

	NHI covered			NHI non-covered
Drug Category	PE 1 (Standard HTA)	PE 2 (MEA) or (RSA, risk sharing agreement)	EEE (PE Exempt Category	Drug approved, but not covered by NHI
Drug Status	Standard category (started in 2007)	Lack of therapeutically equivalent comparator Drugs under high level of clinical uncertainty, due to -low data quality, -lack of direct comparative data, -single arm study, -surrogate outcome, -short-term evidence, -small sample size (introduced in 2014)	Lack of therapeutically equivalent comparator Anti-cancer & rare disease drugs, -lack of clinical data -listed in more than three A7 countries (introduced in 2015)	-No attempt of PE, or -PE attempted but price negotiation with NHIS failed

Classification of Drugs - continued

	NHI covered			NHI non-covered
Drug Category	PE 1 (Standard HTA)	PE 2 (RSA or MEA)	PE Exempt (EEE)	
Pricing	HTA and NHIS (NHI Service) negotiation	Two schemes 1) performance based agreement - CED, CTC 2) finance based agreement - refund, expenditure cap, volume cap	-price set as lower than the lowest of A7 prices -expenditure cap applied	Market price charged by drug companies

note i) EEE, exemption system for economic evaluation data submission; WAP, weighted average price of comparators; CED, coverage with evidence development; CTC, conditional treatment continuation; A7, 7 advanced countries including US, UK, France, Switzerland, Italy, Germany, and Japan

note ii) In Korea, most of MEA drugs are in the 'refund(double pricing)' contract in the 'finance based' category

HTA proposed in 2006, and introduced in 2007

After HTA introduced, some changes made in the coverage scheme

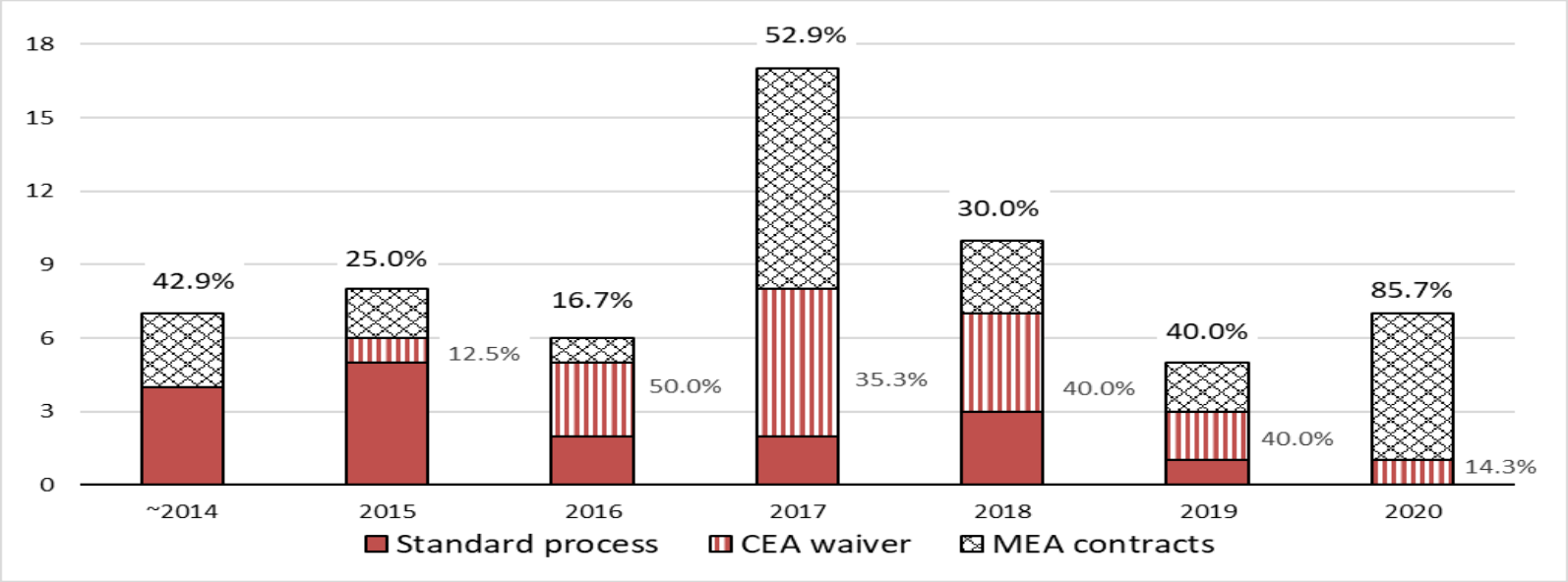
- Flexible ICER threshholds applied
- Introduction of MEA (managed entry agreements) (2014~), to improve patient access to drugs under high and complex level of clinical uncertainty
- Introduction of EEE (Exemption System for Economic Data Submission) (2015~) to improve patient access to drugs (anti-cancer & rare disease drugs) which lacks sufficient clinical data

note i) Korea is known to be the first country using EEE scheme

note ii) In Korea, MEA is being labeled as 'Risk Sharing Agreement'

MEAs & EEEs in Korea

- Introduced in 2014 and in 2015
- Finance-based contracts preferred/superseded
- Listed under uncertainties in effectiveness
- Becoming the norm, not exceptional pathway, for cancer/orphan drugs



Number of listed medicines for cancers or rare diseases by year (2014-2020)

Source, Kim HM, Kwon HY, et al., "Introduction of managed entry agreements in Korea: Problem, policy, and politics" Frontiers in Pharmacology, April 2023, DOI 10.3389/fphar.2023.999220; Diagram by Kwon HY (2025),

Finance-based MEAs

- Expenditure cap
  - Refund E_Δ to the NHI
    - $E_\Delta = E_{actual} - E_{capped} = P * Q - E_{capped}$, if $E_{acutal} > E_{capped}$
- Refund (most preferred contract) : Dual pricing system
  - Refund E_Δ to the NHI
    - $E_\Delta = (P_{list} - P_{real}) * Q_{actual}$
- Utilization cap per patient(volume cap)
  - Refund E_Δ to the NHI
    - $E_\Delta = P * (Q_{actual} - Q_{capped})$, if $Q_{actual} > Q_{capped}$

note 1) E, expenditure; P, price, ; Q, quantity
note 2) As of 2025, all MEA drugs in Korea are in the Finance-based 'Refund' category

Implications

- Improved access to medicines (of uncertain clinical effectiveness, though)

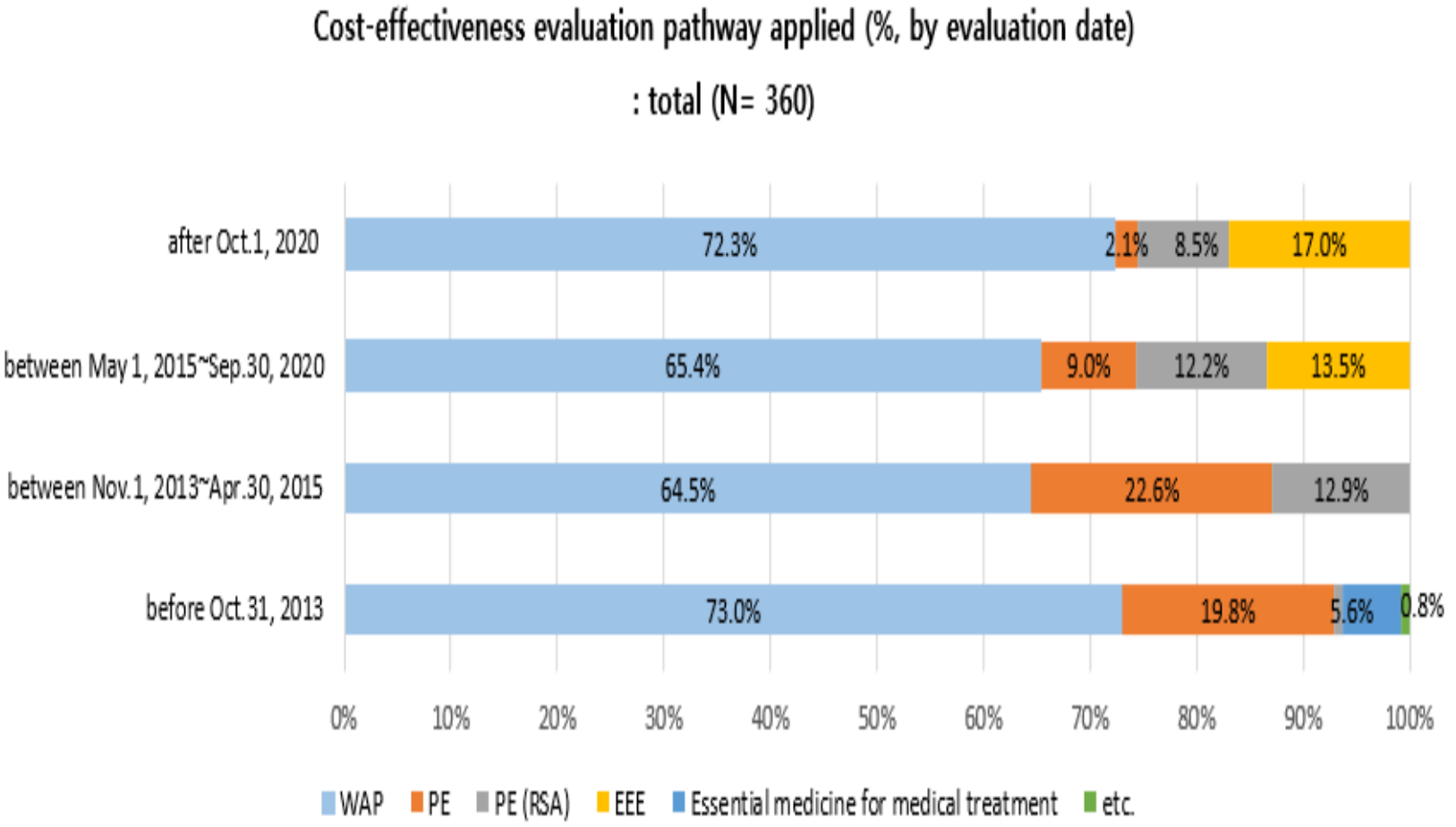
- Transparency in pricing
- Patient copayment
- Administration costs
  - NHIS identifies and pays back to each patient(case of 'refund' type)
- Uncertainties in effectiveness
- Follow-up monitoring with RWD needed

Trade-off?

Note: Currently, under the refund system, the real price (<list price) is known only between drug supplier and the NHIS

PE Evaluation Pathway Applied, Changes after EEE

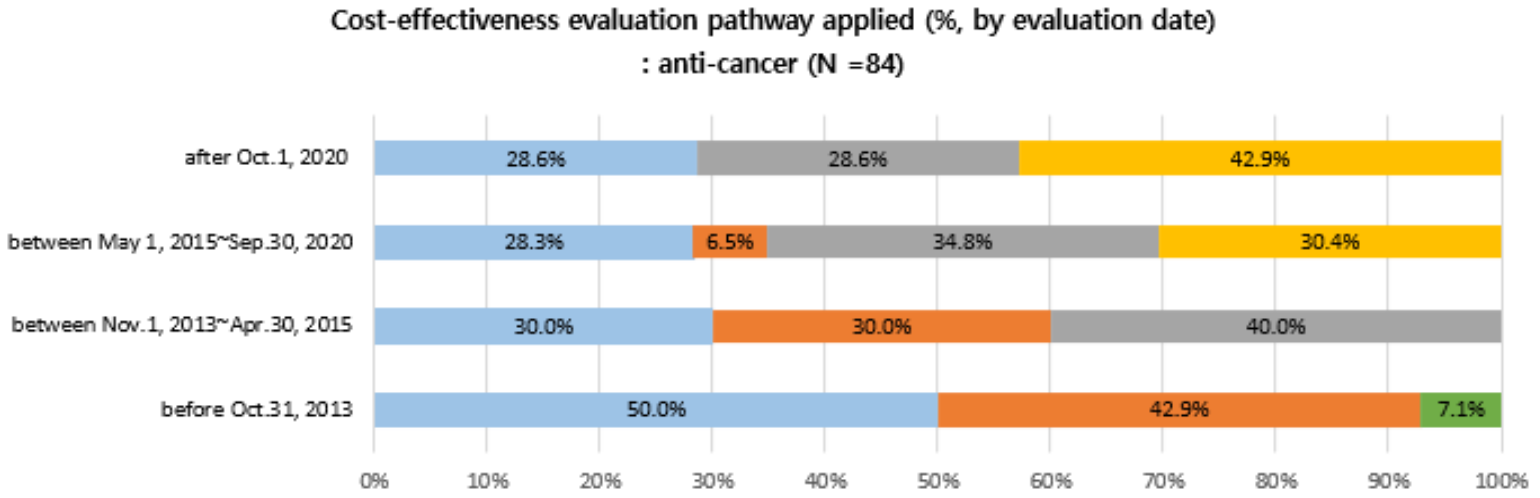
Value Health. 2025; 28(8):1185–1194

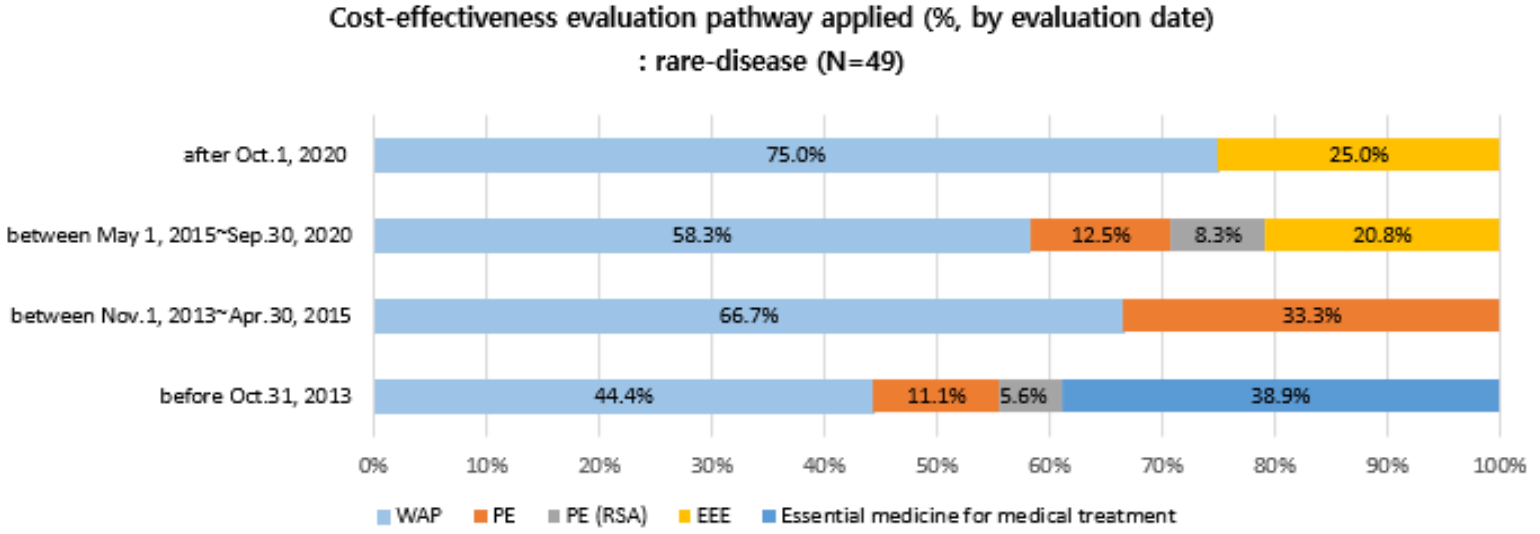


notes: WAP (weighted average pricing) = those drugs of no need for PE evaluation, PE = drugs of standard PE(HTA) evaluation, PE(RSA) = RSA drugs done with PE review, EEE = PE exempt drugs

Changes in Evaluation Pathway

Value Health. 2025; 28(8):1185–1194





PE Evaluation Rates Dropped after Introducing EEE (Exempt) Category

Value Health. 2025; 28(8):1185–1194

- PE (standard CEA) evaluation dropped
  - 35.5% -> 21.1% -> 10.6%
- Instead, (CEA exempt) EEE category drugs gradually increased
  - 13.5% -> 17.0%
- Anti-cancer drugs
  - PE, 70.0% -> 41.3% -> 28.6%
  - EEE, 30.4% -> 42.9%
- Rare Disease drugs
  - PE, 33.3% -> 20.8% -> 0%
  - EEE, 20.8%->25.0%

Note: Fine with improved patient access to anti-cancer and rare disease drugs. But, where is the 'value for money' principle going?

Financial Impact of Using EEE

Value Health. 2025; 28(8):1185–1194

Items of budgetary impact	EEE		RSA (MEA)		PE	
		follow-on		follow-on		follow-on
Number of ingredients	27	5	26	7	16	2
Pharmaceutical expenditure (million USD)	135.08	60.32	662.35	129.36	87.03	4.86
Number of patients	3403	2887	54 194	13 124	18 672	781
Cost per person (K USD)	32.87		12.11		4.78	

Notes:
-expenditure per year, and patients per year
-for comparison, PE category includes only anti-cancer and rare disease ingredients
-follow on: secondary group of EEE (RSA) drugs introduced on top of existing EEE (RSA) drugs, i.e. (後續藥劑)

Drug Expenditures after Adopting EEE

Value Health. 2025; 28(8):1185–1194

- EEE drug expenditure
  - 2017->2022, annual growth rate was 35.59%
  - After 2019년, among the three categories of PE, MEA(RSA), and EEE, EEE expenditure continuously exceeded 15%, i.e., relatively larger expenditure share of those 3 categories
- Compared to MEA(RSA) and PE drugs
  - –Number of patients and total drug expenditure the highest under MEA(RSA)
  - –However, per patient drug exp is the highest under EEE, which is 2.13~3.19 times of MEA, and 6.07~8.52 times of PE, (during the period of 2017~2022)

For EEE and MEA(RSA) Classified Drugs in Korea, in Many EU Countries, Value for Money Checked through PE Evaluations

Lee TJ etc., What can be done to improve the value for money aspects of EEE products, HIRA, 2023

	UK(NICE)	Australia(PBAC)	Canada(CDA)	Scotland(SMC)
Evaluation done	28 / 36 (78%)	26 / 36 (72%)	30 / 36 (83%)	27 / 36 (75%)
Listing recommended	27 / 28 (96%)	22 / 26 (85%)	28 / 30 (93%)	24 / 27 (89%)
HTA done by	28 / 28 (100%)	25 / 26 (96%)	30 / 30 (100%)	25 / 26 (96%)
• CUA	28 (100%)	17 (68%)	30 (100%)	24 (96%)
• CEA	0 (0%)	2 (8%)	0 (0%)	0 (0%)
• CMA	0 (0%)	6 (24%)	0 (0%)	1 (4%)

note: It is to be noted that, through HTA, most of the 'listing recommended' drugs were asked to supplement clinical outcome data afterward (NICE-27, PBAC-22, CDA-28, SMC-19)

EEE, Exemption system for Economic Evaluation data submission for pharmaceuticals; RSA, Risk-sharing agreements; CUA, Cost-utility analysis; CEA, Cost-effectiveness analysis; CMA, Cost-minimization analysis; NICE, National Institute for Health and Care Excellence; PBAC, Pharmaceutical Benefits Advisory Committee; CDA, Canada's Drug Agency; SMC, Scottish Medicines Consortium

Issues to be Questioned

- Are the rising costs stemming from MEA, and in particular from EEE coverage, could be justified within the Korean health care system context?

  - For example, in UK, spending for new drugs during 2000~2020 generated 3,75million QALYs whereas same amount of financing could have generated 5.00million QALYs when if used for other health services. In other words, **the net health effect** of new drug financing during 2000-2020 was **minus 1.25million QALYs** in UK (Naci et al. The Lancet 405. 10472, 2025).

  - That is, paying high prices for new drugs without considering **value for money** can adversely affect population health

Issues to be Questioned

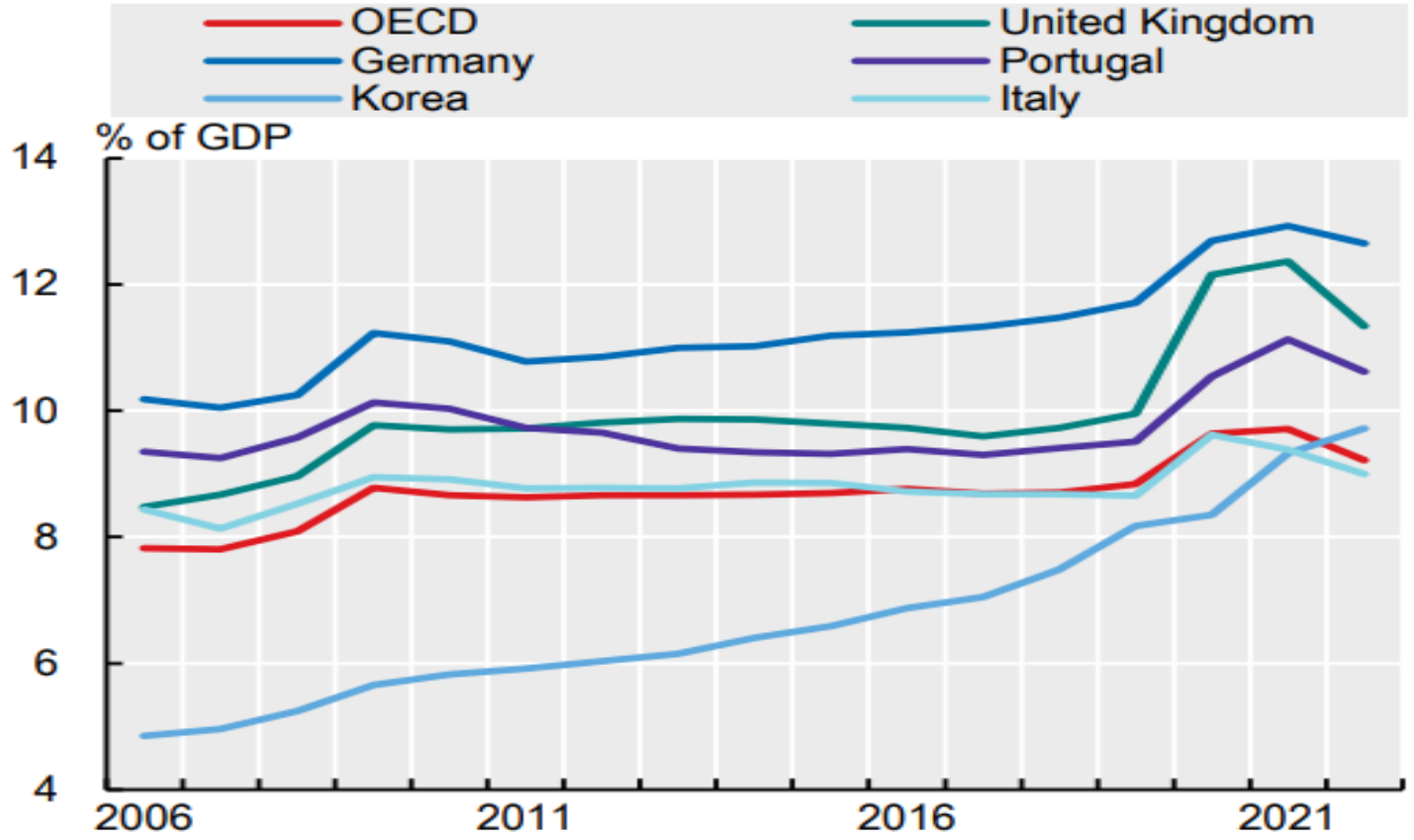
- In coverage of both EEE (PE exempt) and MEA ('refund' category in reimbursement) drugs in Korea, one hardly finds signs of pursuing value for money
  - Through K-NHI coverage of EEE and MEA new drugs, access to anti-cancer and rare disease drugs improved
  - But producing further clinical effectiveness and encouraging reducing health outcome uncertainty seldom happens
- The pursuit of "value for money" has largely been lost, yet the long-term efficiency of healthcare financing remains a critical issue

<Additional reference>

Sustainability of Korean National Health Insurance System continuously challenged

National Health Expenditure and Drug Expenditure, after Introduction of PLS (2007), & MEA(2014), & EEE(2015)

Figure 7.3. Health expenditure as a share of GDP, selected countries, 2006-22



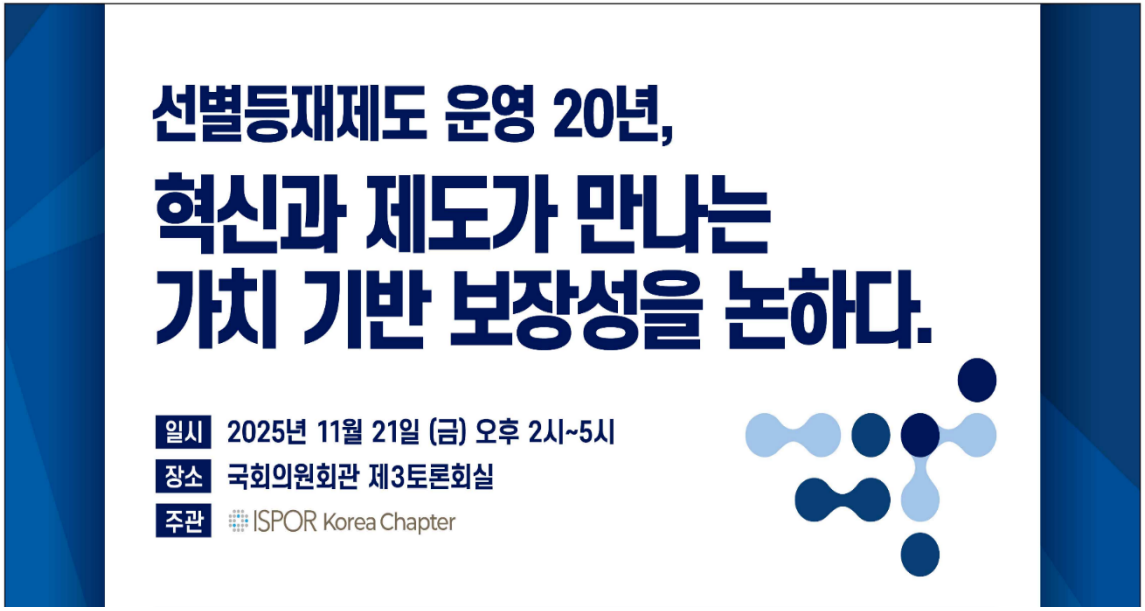
Source: OECD Health Statistics 2023; WHO Global Health Expenditure Database

National Health Expenditure and Drug Expenditure, Korea, recent years

	Korea	US	UK	Japan	France	Germany	Italy	Swiss	Australia	Canada	Belgium	Netherlands	Spain	Sweden
Drug exp. Annual growth rate (`15-`22, %)	5.50 %	1.79 %	-0.03 %	-1.12 %	-0.11 %	2.18 %	0.52 %	3.62 %	3.84 %	1.70 %	-0.74 %	-0.22 %	1.66 %	1.50 %
Drug/NHE (`2022, %)	18.33 %	12.08 %	9.56 %	15.89 %	13.00 %	13.4 %	17.3 %	11.9 %	12.6 %	14.6 %	10.3 %	6.67 %	15.2 2%	9.55 %

Source: OECD Health Statistics 2023; WHO Global Health Expenditure Database

Discussion Session on PLS, at the Korea National Parliament, 2025.11.21 (Fri.)



Session Topic:
Discussion on ‘value based management(pricing) under 20 years of PLS, looking back and looking forward’