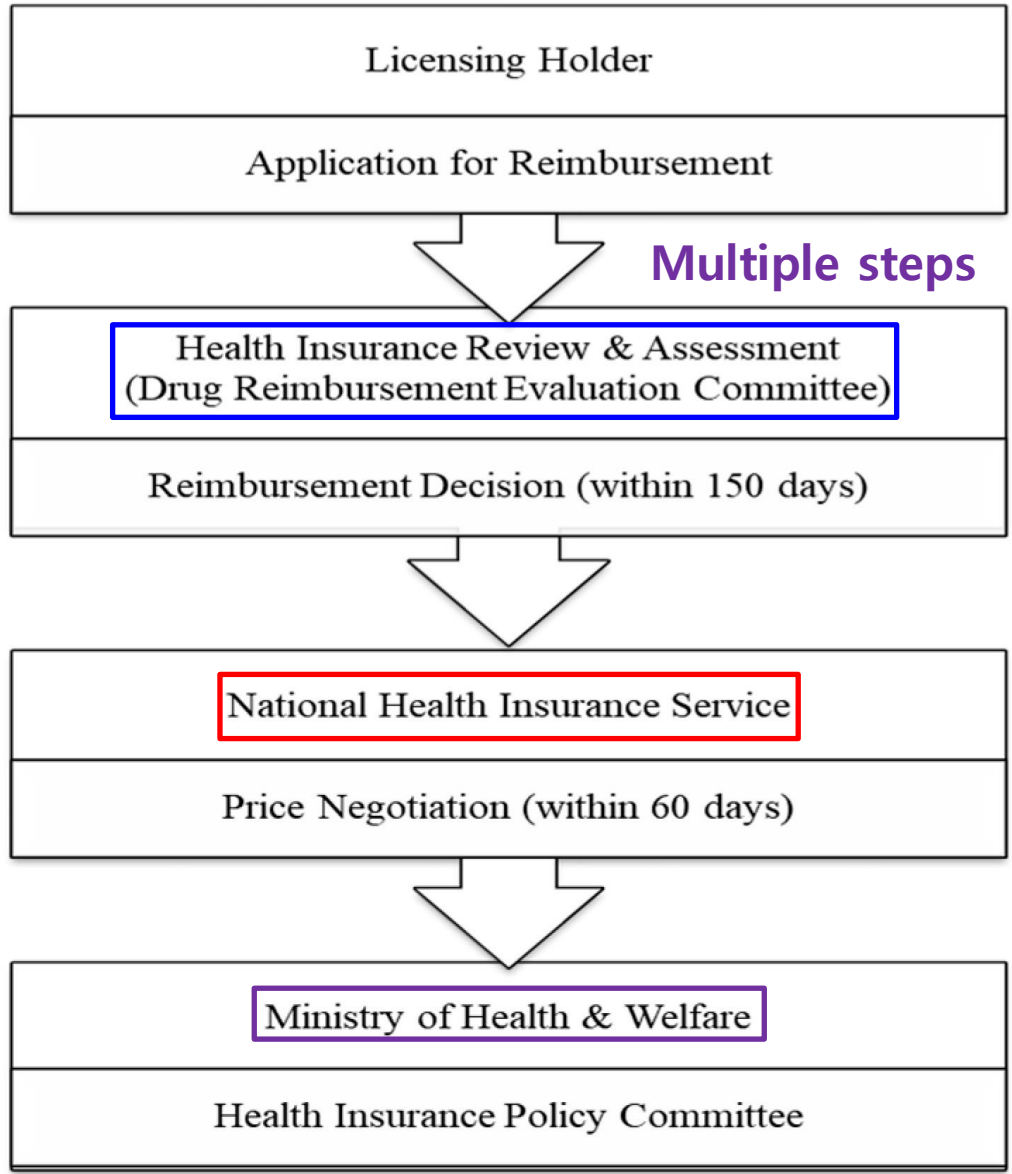# New Drug Expenditure
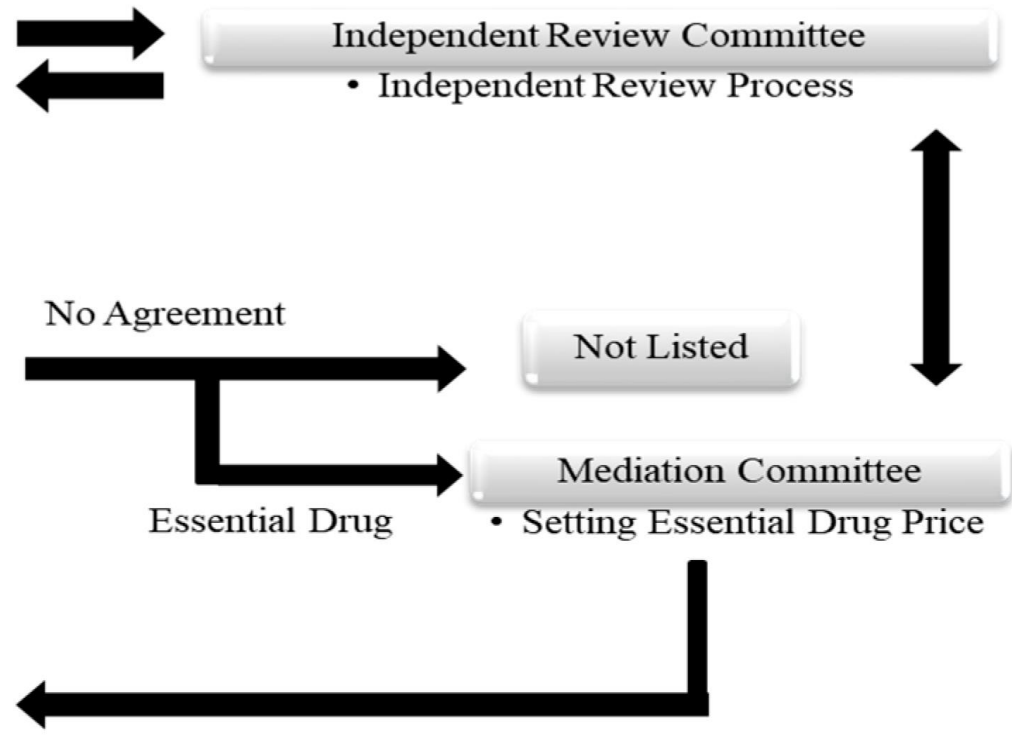# by Therapeutic Area in South Korea

International Comparison and Policy Implications

Seung-Rae Yu (Ph.D. in Health Social Pharmacy)
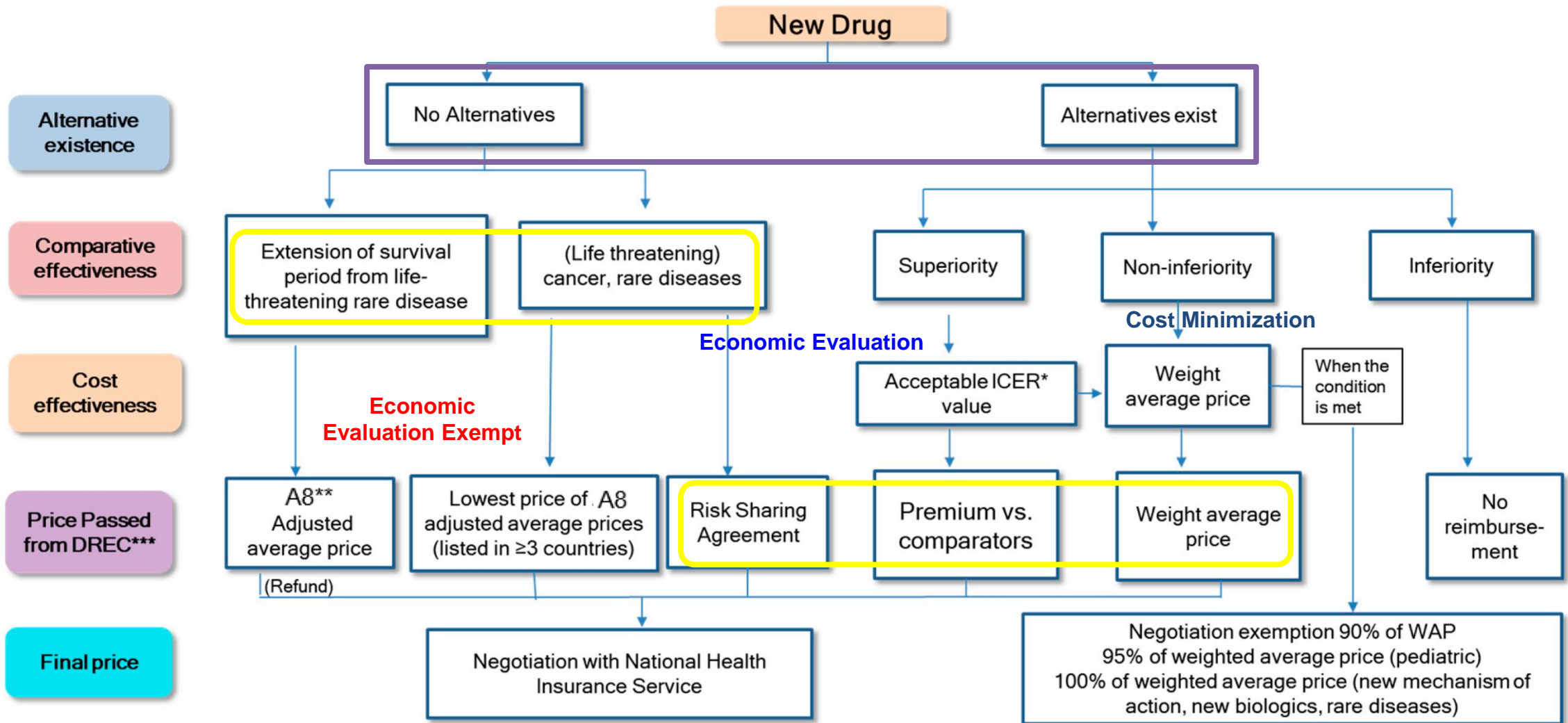**College of Pharmacy, Dongduk Women's University**

Listing Procedure for New Drugs in NHI

KRPIA
Korean Research-based Pharma Industry Association

KPBMA
Korea Pharmaceutical and Bio-Pharma Manufacturers Association

Licensing Holder

Application for Reimbursement

Multiple steps

HIRA

Health Insurance Review & Assessment (Drug Reimbursement Evaluation Committee)

Reimbursement Decision (within 150 days)

h·well NHIS
National Health Insurance Service

National Health Insurance Service

Price Negotiation (within 60 days)

Ministry of Health and Welfare

Ministry of Health & Welfare

Health Insurance Policy Committee

❖ **Drug Expenditure Rationalization Plan (2007)**

➢ **HIRA: Clinical & Economic assessment (Value evaluation)**

➢ **NHIS: Price negotiation & agreement (NHI listing contract)**

Independent Review Committee
• Independent Review Process

No Agreement → **Not Listed**

Essential Drug → **Mediation Committee**
• Setting Essential Drug Price

Yu, SR et al. Improving Patient Access to New Drugs in South Korea: Evaluation of the National Drug Formulary System. Int. J. Environ. Res. Public Health 2019, 16, 288.

Evaluation Process for New Drug

* Incremental Cost Effectivess Ratio

** USA, Japan, UK, Germany, France, Swiss, Italy, Canada

*** Drug Reimbursement Evaluation Committee of HIRA

Yu, SR et al. Improving Patient Access to New Drugs in South Korea: Evaluation of the National Drug Formulary System. Int. J. Environ. Res. Public Health 2019, 16, 288.

❖ **Current Challenges**

✓ **Since 2007**, Korea has managed **total drug spending at 24% of total medical costs.**

✓ But there is **no clear strategy** for **allocating new drug spending** within this budget.

➢ **Key Objectives**

✓**Compare New Drug Spending**: how **Korea**'s new drug spending compares to **other countries**.

✓**Analyze Therapeutic Focus**: how drug spending **aligns with disease burdens** worldwide.

✓**Evaluate Policy Impact**: how **patient access policies affect** new drug **availability**.

➤ Focus on **New Chemical Entities (NCEs)** impacting patient access and costs.

➤ Collect **New Drug Listings worldwide since 2007** **(Korea's positive list system launch year)**

➤ Analyze **spending (2017–2022) using ATC Level 1,** and compare NCE distribution at ATC 2 & 3.

ATC (Anatomical Therapeutic Chemical Classification System)

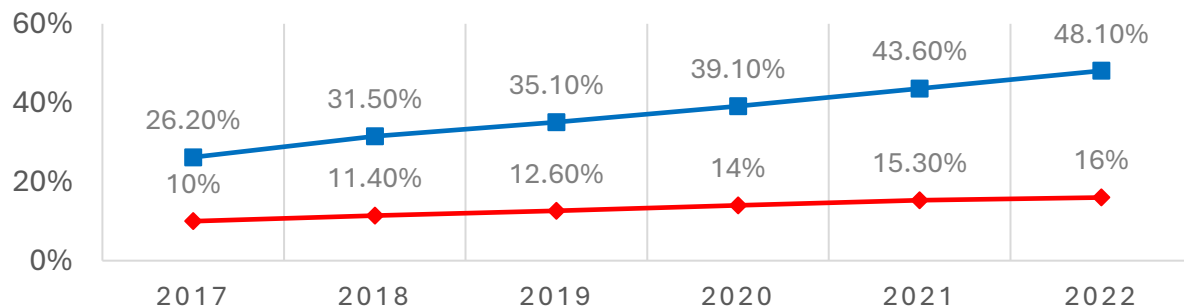| Level	Classification	ATC Classification Example	
1st	Anatomical main group	A	Alimentary tract and metabolism
2nd	Therapeutic subgroup	A10	Drugs used in diabetes
3rd	Pharmacological subgroup	A10B	Blood glucose lowering drugs, excl. insulins
4th	Chemical subgroup	A10BA	Biguanides
5th	Chemical substance	A10BA02	Metformin

Research Overview

• **Comparison Countries**: Korea, A8* and OECD countries**
  * **A8** countries: USA, Japan, UK, Germany, France, Swiss, Italy, Canada
  ** **OECD**: A total of **26 countries** with comparable drug cost data.

• **Analysis Period**: 2017-2022 (the total of recent 6 years)

• **Targets**: New drugs(NCE)*** listed between 2007 2022
  *** NCE refers to New Chemical Entities based on active ingredients

  ※ Main Source of Analysis Data

  : National Health Insurance Medical Expenses/Drug Expenditures
    (e.g., Reimbursed Drug Claims Data)
  : IQVIA MIDAS® Quarterly Sales Value data, 2017-2022,
  : WHO ATC Index (e.g., Reimbursed Drug ATC Matching File)

International Comparison of New Drug Expenditure Share

APAC
Asia Partnership Conference
of Pharmaceutical Associations

Trends in the proportion of new drug expenditure in Korea and A8

* Share of new drug expenditure in total drug spending ●—Korea ●—A8 Average

A8 Average: 26.20% (2017), 31.50% (2018), 35.10% (2019), 39.10% (2020), 43.60% (2021), 48.10% (2022)

Korea: 10% (2017), 11.40% (2018), 12.60% (2019), 14% (2020), 15.30% (2021), 16% (2022)

[Korea] Number of listed new drugs from 2007 (after the introduction of Drug Expenditure Rationalization Plan) to 2022: **276**

[OECD] Number of new drugs approved by FDA, EMA, PMDA and introduced in OECD countries between 2007 and 2022: **639**

❖ **New Drug Expenditure Proportion (from 2017 to 2022, average)**
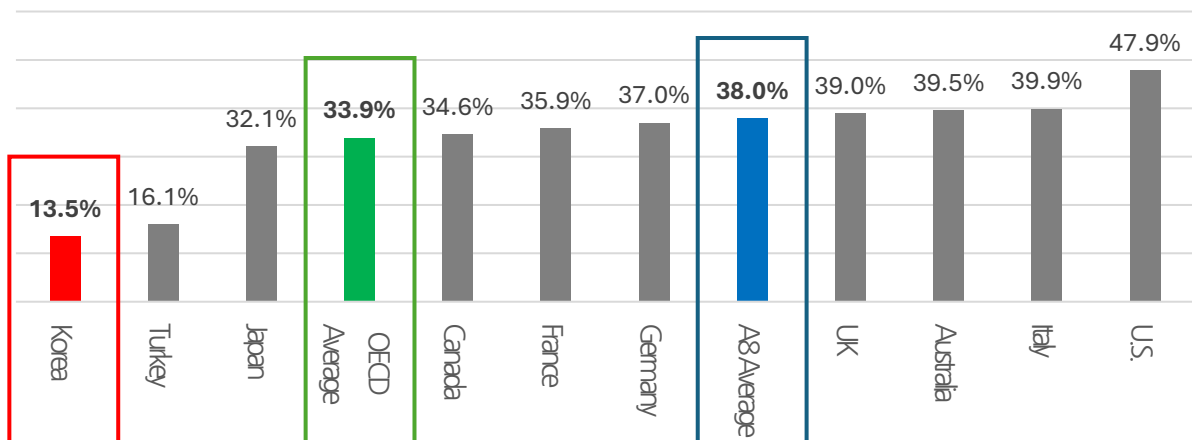   **: (A8 Countries Average) 38.0% ↔ (Korea) 13.5%**
   ※ Compound Annual Growth Rate(CAGR) of new drug expenditure share
     : A8 Countries Average 13.0% ↔ Korea 9.8%

❖ **The Most Recent Year(2022) New Drug Expenditure Proportion**
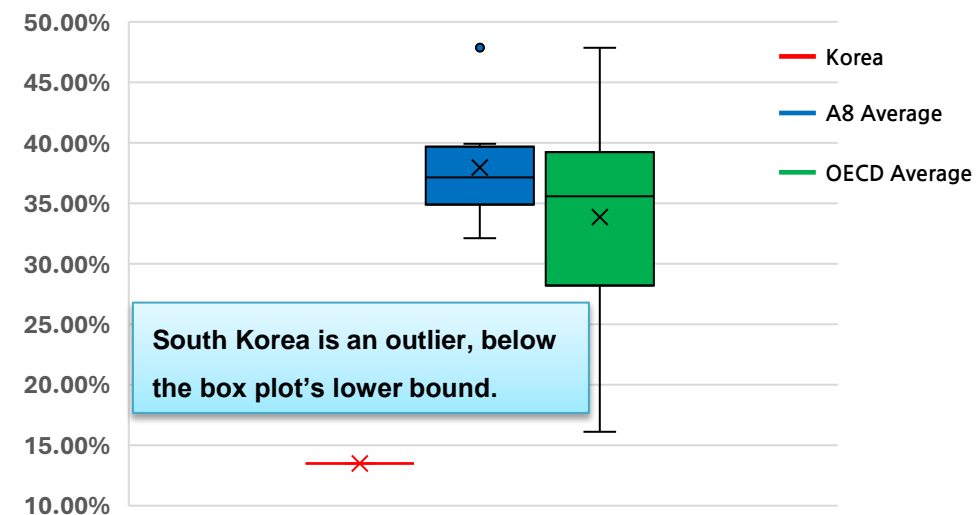   **: (A8 Countries Average) 48.1% ↔ (Korea) 16.0%**

Proportion of new drug expenditure in Korea, A8, and OECD

* share of new drug expenditure in total drug spending

Korea 13.5%, Turkey 16.1%, Japan 32.1%, OECD Average 33.9%, Canada 34.6%, France 35.9%, Germany 37.0%, A8 Average 38.0%, UK 39.0%, Australia 39.5%, Italy 39.9%, U.S. 47.9%

※ Cumulative from 2017-2022

Box plot of new drug expenditure share in Korea, A8, and OECD

— Korea
— A8 Average
— OECD Average

South Korea is an outlier, below the box plot's lower bound.

※ Cumulative from 2017-2022

Global Burden of Disease (GBD) Indicators: Disability-Adjusted Life Year (DALY)

Legend: — Korea — A8 average

Chart data (Korea / A8 average):

Disease group	Korea	A8 average
Respiratory infections and tuberculosis	3.80%	6.80%
Digestive diseases	3.80%	3.30%
Self-harm and interpersonal violence	4.10%	1.80%
Unintentional injuries	5.60%	4.90%
Neurological disorders	7.10%	8.20%
Mental disorders	7.20%	7.90%
Diabetes and kidney diseases	8.10%	5.10%
Cardiovascular diseases	11.70%	14.40%
Musculoskeletal disorders	13.10%	10.30%
Neoplasms	17.00%	17.40%

✓ Not only in Mortality, but also in Disability-adjusted life year (DALY), **Neoplasms ranks top position**.
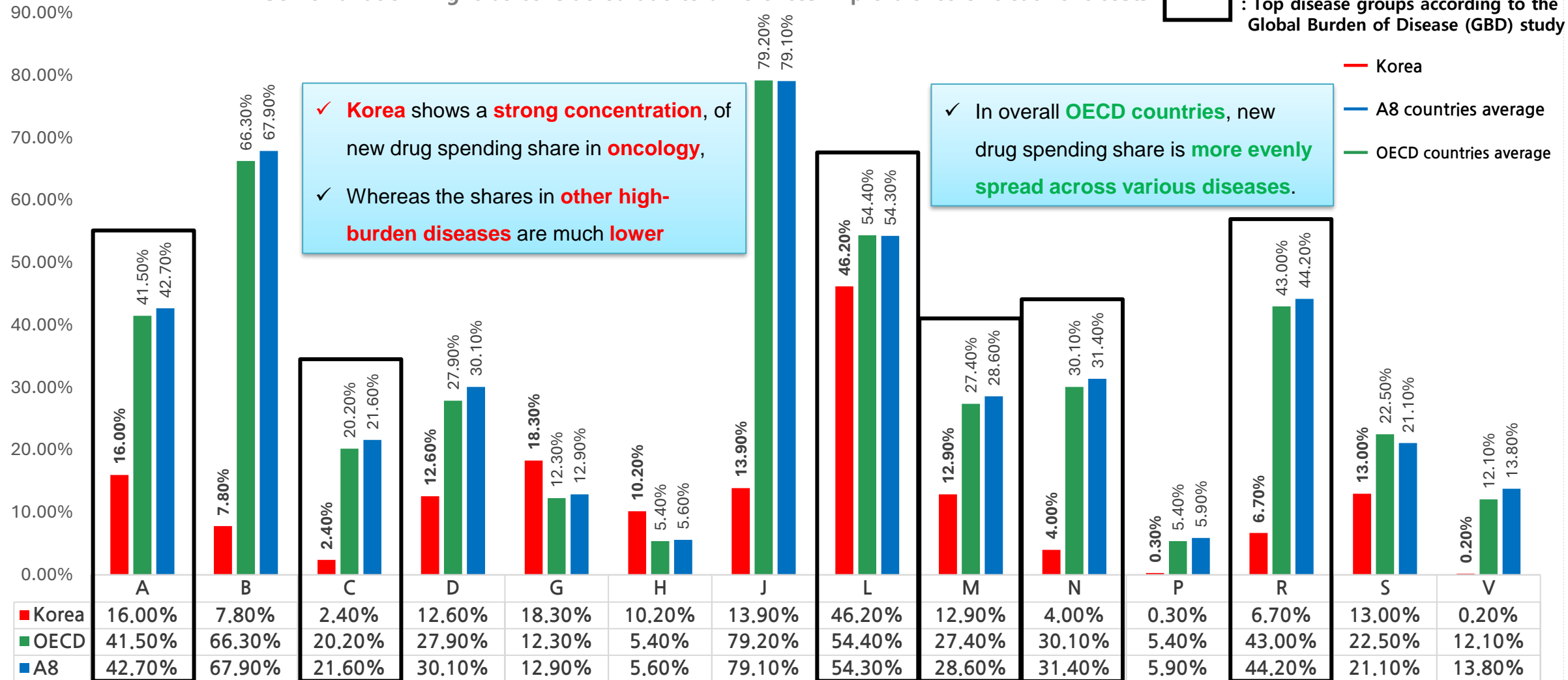
✓ But **musculoskeletal and other groups also show a high burden**.

➢ **Access to innovative treatments** should be **balanced**, across **various disease groups**.

New Drug Expenditure Proportion by Therapeutic Area

APAC
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of Pharmaceutical Associations

* Some variation might be considered due to differences in prevalence or treatment costs

☐ : Top disease groups according to the Global Burden of Disease (GBD) study

- Korea
- A8 countries average
- OECD countries average

✓ **Korea** shows a **strong concentration**, of new drug spending share in **oncology**,

✓ Whereas the shares in **other high-burden diseases** are much **lower**

✓ In overall **OECD countries**, new drug spending share is **more evenly spread across various diseases**.

	A	B	C	D	G	H	J	L	M	N	P	R	S	V
Korea	16.00%	7.80%	2.40%	12.60%	18.30%	10.20%	13.90%	46.20%	12.90%	4.00%	0.30%	6.70%	13.00%	0.20%
OECD	41.50%	66.30%	20.20%	27.90%	12.30%	5.40%	79.20%	54.40%	27.40%	30.10%	5.40%	43.00%	22.50%	12.10%
A8	42.70%	67.90%	21.60%	30.10%	12.90%	5.60%	79.10%	54.30%	28.60%	31.40%	5.90%	44.20%	21.10%	13.80%

Conclusions and Recommendations

❖ Key Findings

✓ **Korea's drug expenditure policies** support **budget sustainability** but also **limit access to new drugs**.

✓ **The share of new drug spending (13.5%)** remains **much lower** than A8 (38.0%) and OECD (33.9%) averages.

✓ There are clear **spending gaps** by **disease area**, along with **limited application** of special tracks (e.g. RSA).

❖ Policy Directions

These can be achieved through continued collaboration among stakeholders

✓ **Strengthening coverage for severe diseases and high-cost treatment** to reduce the disease burden.

✓ **Expanding strategic tools such as RSA & PE Exempt for various diseases** to enhance health equity.

✓ **Prioritizing budget allocation for innovative new drugs** that meet Universal Health Coverage goals.

Thank you

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