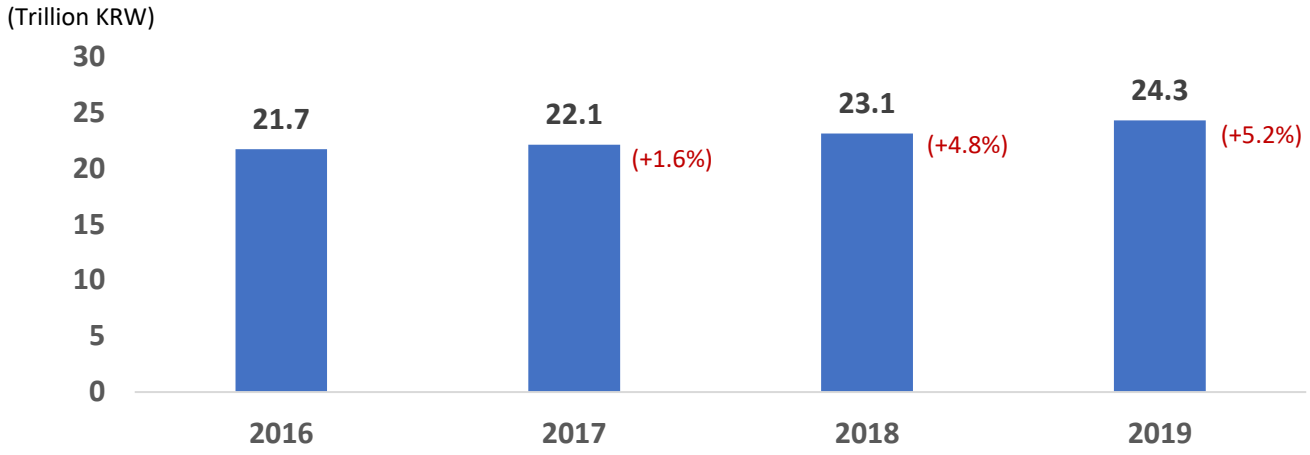
Key Market Challenges and Regulatory Landscape of Pharma Industry

April 9th, 2021

Youngshin Lee

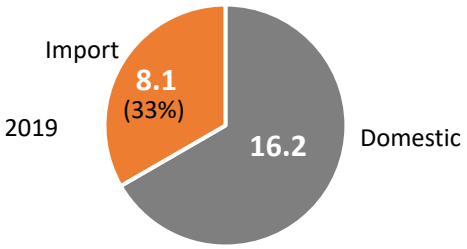
KRPIA
Korean Research-based Pharma Industry Association

Korea Pharma Market (1)

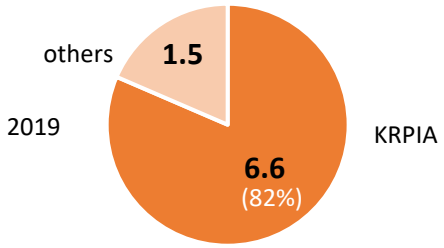


Source – KPBMA report 2020; MFDS report on Aug 3rd, 2020

Import vs. Domestic (Trillion KRW)



KRPIA member contribution (Trillion KRW)

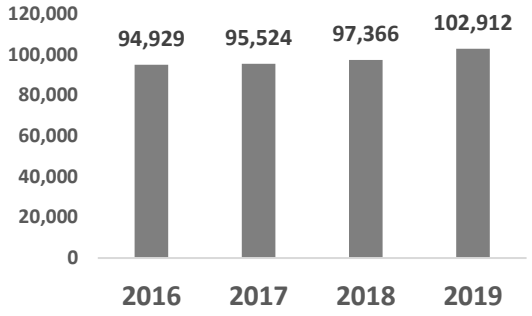


Source – MFDS report, KPBMA report, KRPIA data on file.

Korea Pharma Market (2)

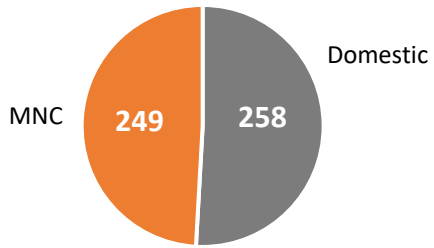
KRPIA

Employment (2019)



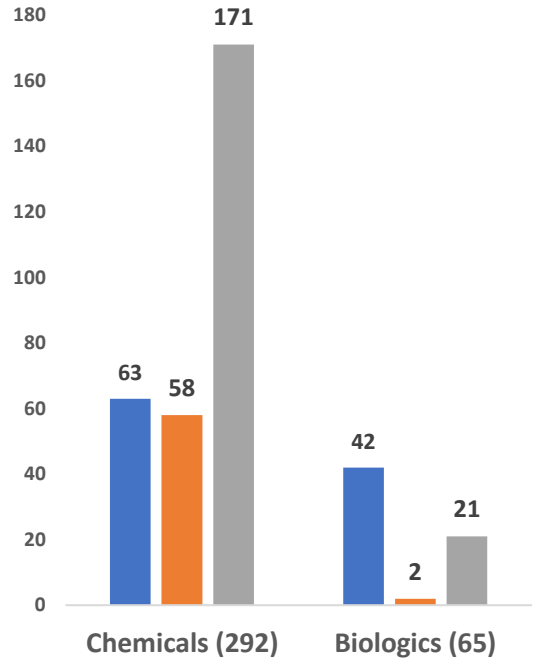
Source – KPBMA report 2020

IND (2019)



Source – MFDS 2020, KoNECT 2020.

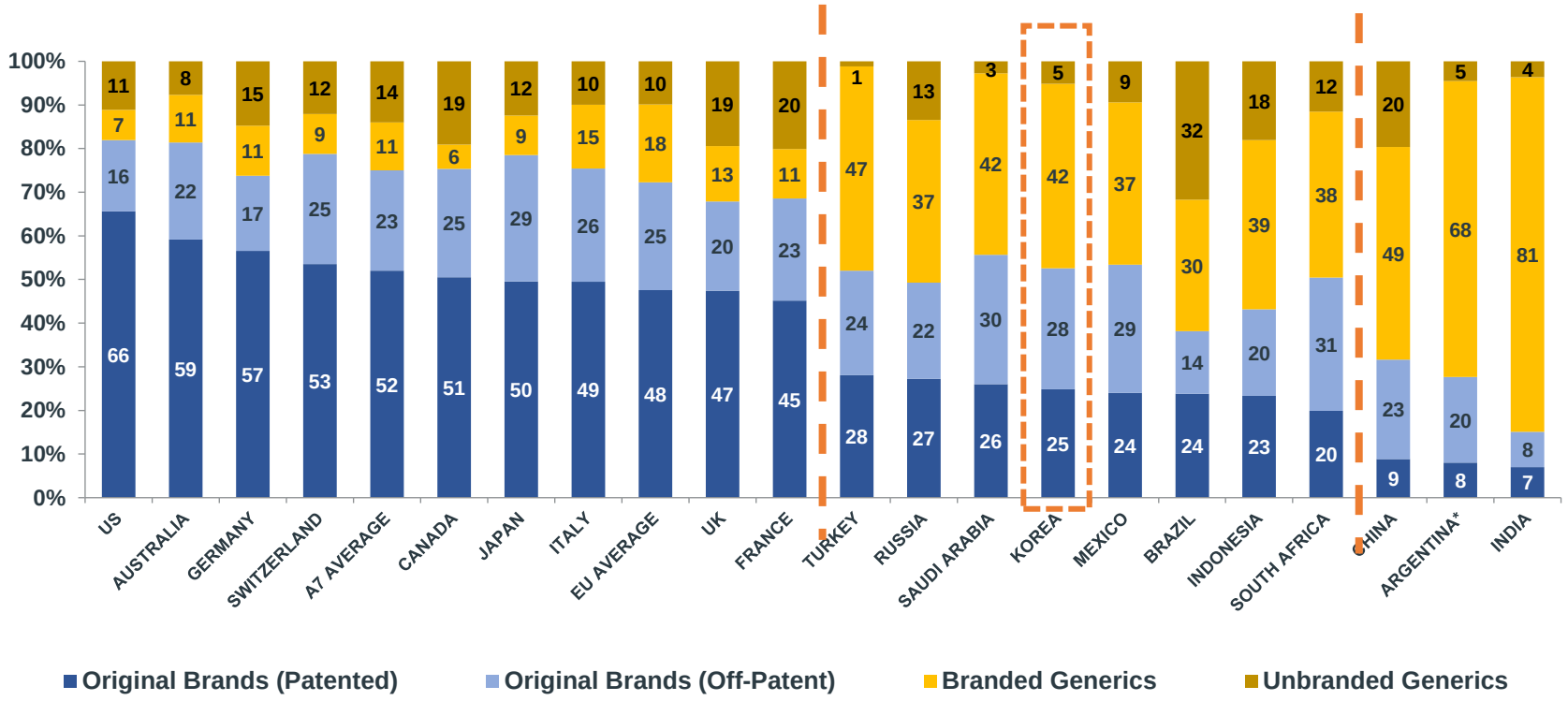
Domestic Pharma R&D – CT Phases (2019)



Source – KoNECT 2020

Share of Prescription Market Sales by Product Segment

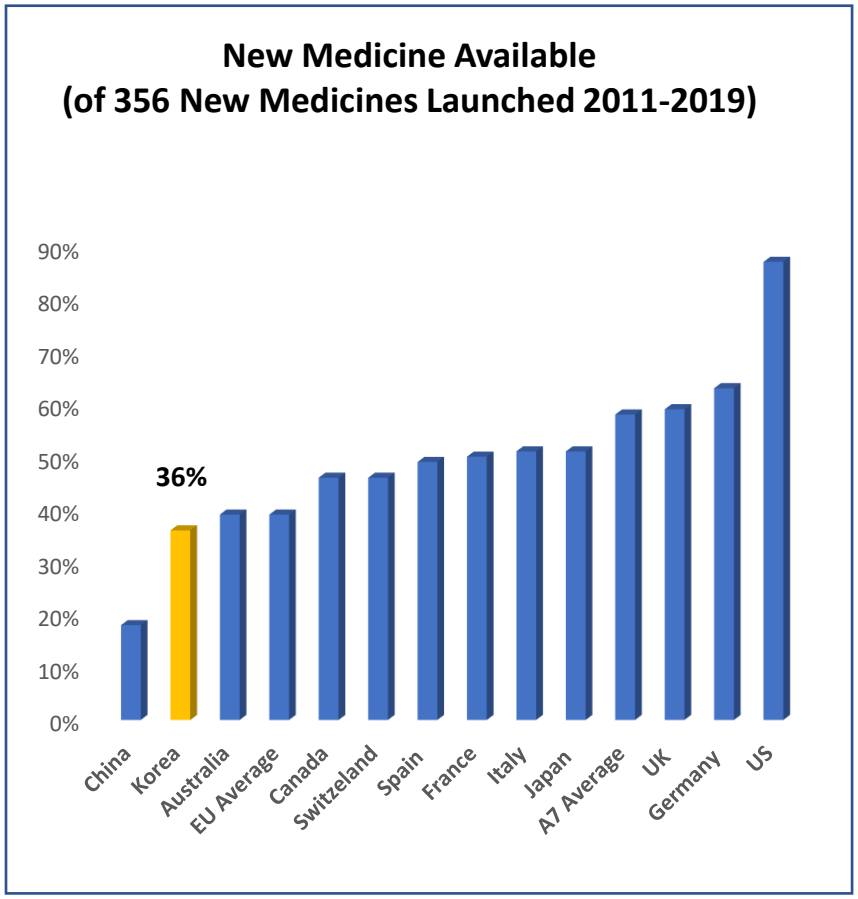
KRPIA

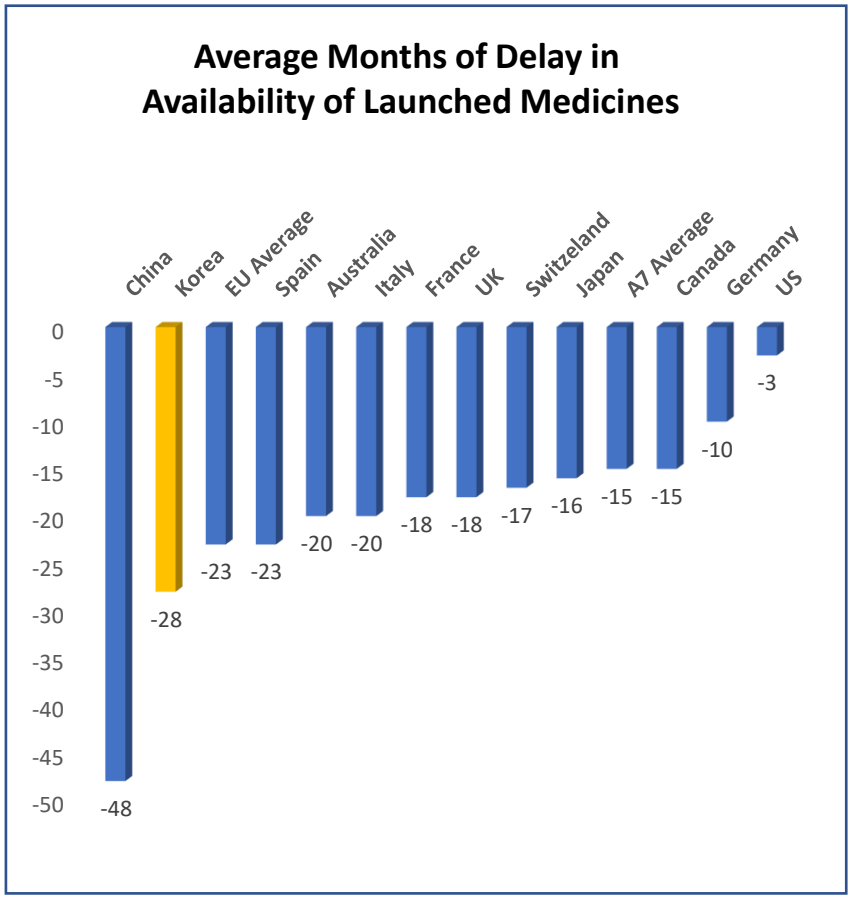


Source: IQVIA analysis of 2018 prescription market sales for PhRMA. April 2020.
Note: Countries which only report the retail channel are marked with an asterisk. A7 countries include France, Germany, Italy, Japan, Switzerland, United Kingdom and United States.

New Medicines Availability

KRPIA





Source : PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data, May 2020

New Medicines and Treatment Choices

KRPIA

	Cancer	Cardiovascular	Vision	Blood	Anti-infectives & Antivirals	Mental Illness
	44%	50%	36%	19%	35%	21%
A7	69%	61%	32%	63%	62%	53%
	96%	71%	82%	100%	88%	94%

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data. May 2020.
Note: New Active Substances approved by U.S. FDA, European Medicines Agency (EMA) and/or Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and first launched in any country between January 1, 2011 and December 31, 2019. A7 countries include France, Germany, Italy, Japan, Switzerland, United Kingdom and United States.

Challenge: NHI P&R Review System

KRPIA

Predictability and Transparency

- P&R review time

By regulations	HIRA data for cancer drugs	Industry data incl. supplementary period
240 – 270 days	**348 days**	**757 days**

Source: Economic Review, 2017

- Rationale/grounds for sub-committee decisions often not disclosed to the sponsor

Challenge: Value of Innovation

KRPIA

Lack of flexibility with ICER (Incremental Cost-Effective Ratio)

- GDP per capita in general with exceptions
- ICER threshold value set to U$23,000, GDP per capita back in 2010, while U$31,800 in 2019, based on World Bank data

Need of new payment model for new innovative treatments

- Immuno-oncology agents, cell/gene therapies – limitation with current RSA(Risk Sharing Agreement) system

Challenge: Promotion of Drug Development Fast Track Review system

KRPIA

	USA	EUROPE	JAPAN	KOREA
	Orphan Drug Designation	Orphan Drug Designation	Orphan Drug Designation	Orphan Drug Designation System exists.
Promotion of drug development	BTD	PRIME Designation	Sakigake Designation	No BTD
Shorten of approval review period	RMAT Designation Fast-Track Priority Review	Accelerated Assessment	Priority Review	There is a Priority Review system, but it is not actually operated.
Exemption of confirmation test		Authorization under Exceptional Circumstance	Accelerated Approval	There is a Fast Track System, but it is actually operated by Accelerated Approval.
Implementation of post-market confirmation test	Accelerated Approval	Conditional Marketing Authorization	Conditional Early Approval Systems	

Leading Country in Bio-Pharma

KRPIA

How to

- Strive for R&D advancement
- Transform to a leading country

Thank you

