



Korea-USA Cooperation in the Health Sector

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I. GVC (Global Value Chain) and Health Sector



1. Executive Order on America's Supply Chains on Feb 24, 2021

For more resilient and secure supply chains for critical and essential goods

100-day review to assess vulnerabilities and areas for improvement of supply chains for 4 areas: pharmaceuticals, rare earth minerals, semiconductor chips, and large-capacity batteries

1-year review of 6 broader supply chains: defense, public health, communications technology, energy, transportation and food production

2. Issues for Health Industry

Section 3 (iv) The Secretary of Health and Human Services, in consultation with the heads of appropriate agencies, shall submit a report identifying risks in the supply chain for pharmaceuticals and active pharmaceutical ingredients and policy recommendations to address these risks

- complementing the ongoing work to secure the supply chains of critical items needed to combat the COVID-19 pandemic, e.g., PPE (personal protective equipment)

e.g., experience of shortage of masks during COVID-19

Issues for Health Industry

APIs (Active Pharmaceutical Ingredients) are the part of a pharmaceutical product that contains the active drug
- more than 70 percent of API production facilitators supplying the U.S. have moved offshore

For drugs regulated by the U.S. Food and Drug Administration, 26% of the manufacturing facilities producing APIs are in the U.S., while 19% of those plants are in India and 13% are in China, and the rest from other foreign countries



3. Impacts on Korea

Uncertainty

It is likely to apply only to those products purchased by federal agencies of the US government

Benefits and costs of driving all drug manufacturing to the US?: A significant portion of APIs and generics are imported from China and India

- No immediate consequences is expected, as the bill is only in a reviewing stage



(Potential) Impact on Export

Negative

- Decline in export

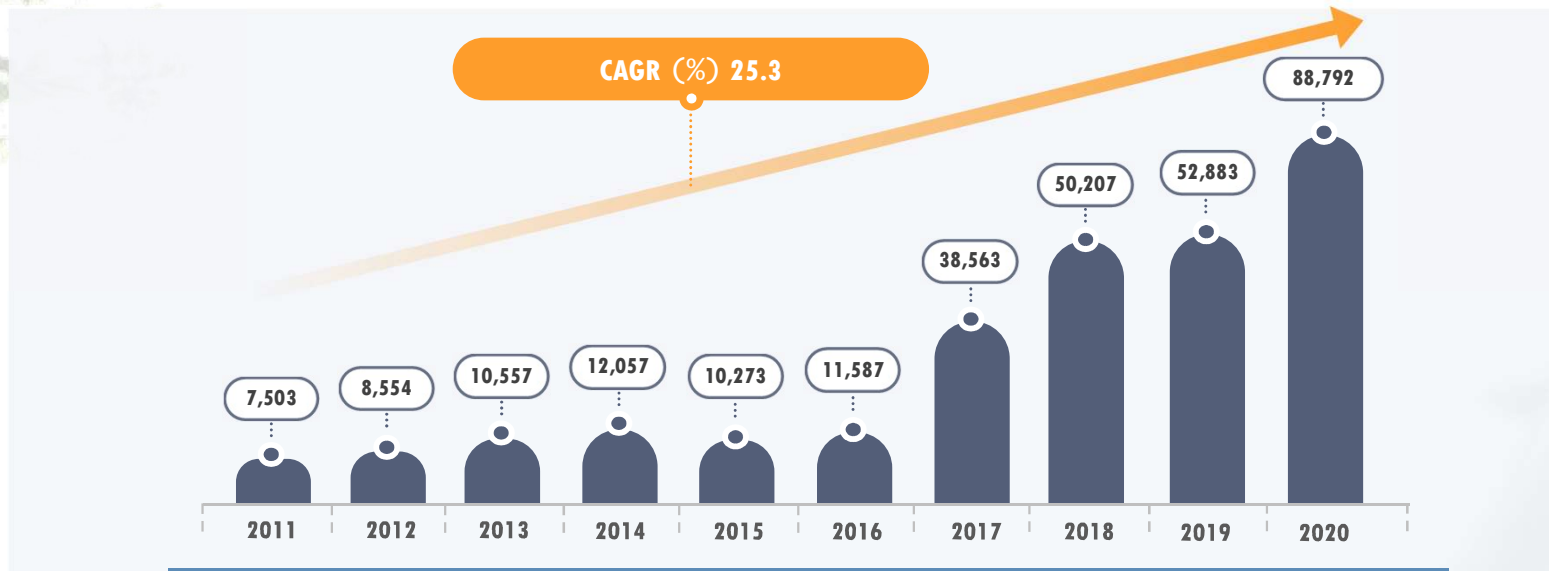
Positive

- if the USA intends to form a global value chain among its allies with decreasing trade from China

Coping Strategy

- **MRA** (Mutual Recognition Arrangement) of GMP (Good Manufacturing Practice):
 - can increase API export to the USA
- R&D cooperation with the USA

Korean Pharmaceutical Export to the U.S. KHIDI Korea Health Industry Development Institute



K-Pharma : Statistics on Pharmaceutical Export to the U.S. (Unit: M\$) (Exchange rate : KRW 1,200 = USD \$1)

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	CAGR ('17~'20)
APIs	58.40	66.96	78.88	88.53	75.30	85.81	66.84	76.12	95.01	107.31	17.1%
Drug Products	16.63	18.58	26.69	32.04	27.43	30.08	318.79	425.95	433.82	780.61	34.8%
Total	75.03	85.54	105.57	120.57	102.73	115.87	385.63	502.07	528.83	887.92	25.3%
(BioPharma)	-	-	-	-	-	-	277.97	373.26	378.24	547.03	32.0%

• Source : ① Ministry of Food and Drug Safety (MFDS), ② KHIDI re-edited ③ 2020&Biopharma : HS Code based calculation



II. UHC (Universal Health Coverage)



In Addition to GVC

President Biden is keen to

- Access to health care
- Support for cancer research and care
- Biopharmaceutical R&D

Role of technology and R&D is expected to increase
e.g., Precision medicine, digital health,
AI for R&D for biopharmaceutical industry

1. UHC (Universal Health Coverage)

Affordable Care Act (Obama Care)

- Access to affordable health insurance

President Trump got rid of the individual mandate law in 2017

- President Biden will bring back ACA in 2021 with several new mandates

Similarity of health care delivery in Korea and the US:
dominant role of the private sector

- Pros: innovations in the private sector
- Cons: cost containment and financial sustainability

2. Value Based Payment

Accountable Care Organization (ACO) in the US

- Network of insurer/purchaser and providers (physicians and hospitals)
- Continuum of care: prevention, acute care (primary care to secondary/tertiary care), post-acute care and rehabilitation, geriatric and long-term care

Payment based on performance and health outcomes

- Outcome measurements
- Incentives and financial risk sharing (between insurer and providers)



3. Benefits coverage and Health Technology Assessment

Decision process for the coverage of innovative medicines and technology

- Which one to be publicly funded and which one to be privately funded?
- Technology assessment: need new paradigm?
- Patient-centeredness

Potential tension between the goals of health policy and industrial policy

- Compensation and incentive for R&D and innovation
- How to ensure affordability and equitable access
- Financial sustainability: pressure to pharmaceutical pricing?



III. Pandemics and Health Security



1. Health Security

Policy learning from the experience of COVID-19

Supply of medicines, PPEs

- GVC, optimal amount of stock, trade

Vaccines: R&D, vaccination, monitoring/surveillance,
HRH (Human resource for health), public acceptance

Policy capacity for preparedness and response to a
pandemic

- testing strategy, contact tracing, legal measures

2. Global Cooperation

Time for the US to play a leading role in global development and health, including health security (again)

- Korea needs to be more actively engaged

Funding for R&D for pandemics as a global public good

Global cooperation and support for the LMICS (low- and middle-income countries)

- For both equity and efficiency

How to improve/ensure access to vaccines and medicines for a pandemic for all people in the world