Introduction of Drug supply stabilization policy in Korea

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Global Challenging Issue, Unstable Supply and Demand

▣ Unstable Pharmaceutical Supply and Demand is Global Challenge

BECKER'S HOSPITAL REVIEW

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Customers stand at the windows buying medicines in a pharmacy in St. Pete

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Drug Shortage Concerns Are Top of Mind Amid COVID-19 Outbreak

March 21, 2020

Caitlin Mollison, Managing Editor

HEALTH

Acquired shortage: India's HIV drugs are in short supply, which could have been averted

This risks undoing India's hard-won gains against HIV/AIDS and further derails the global progress, which is not on track to meet the goal of ending AIDS by 2030

NEXT NEWS >

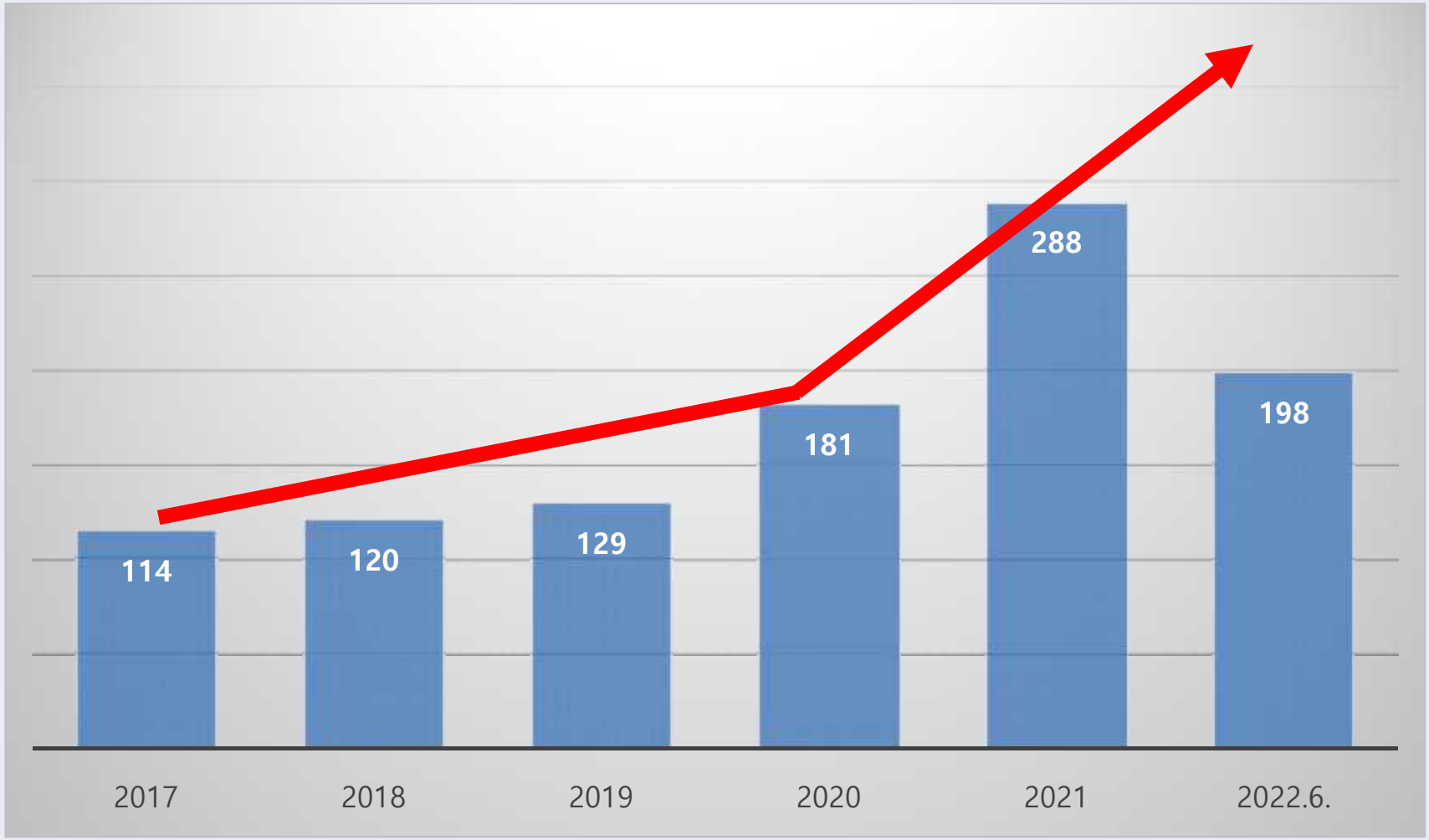
By Taran Deol

Published: Wednesday 24 August 2022

Pizar some the warnings, in messages among friends and families and on social media, to speak up

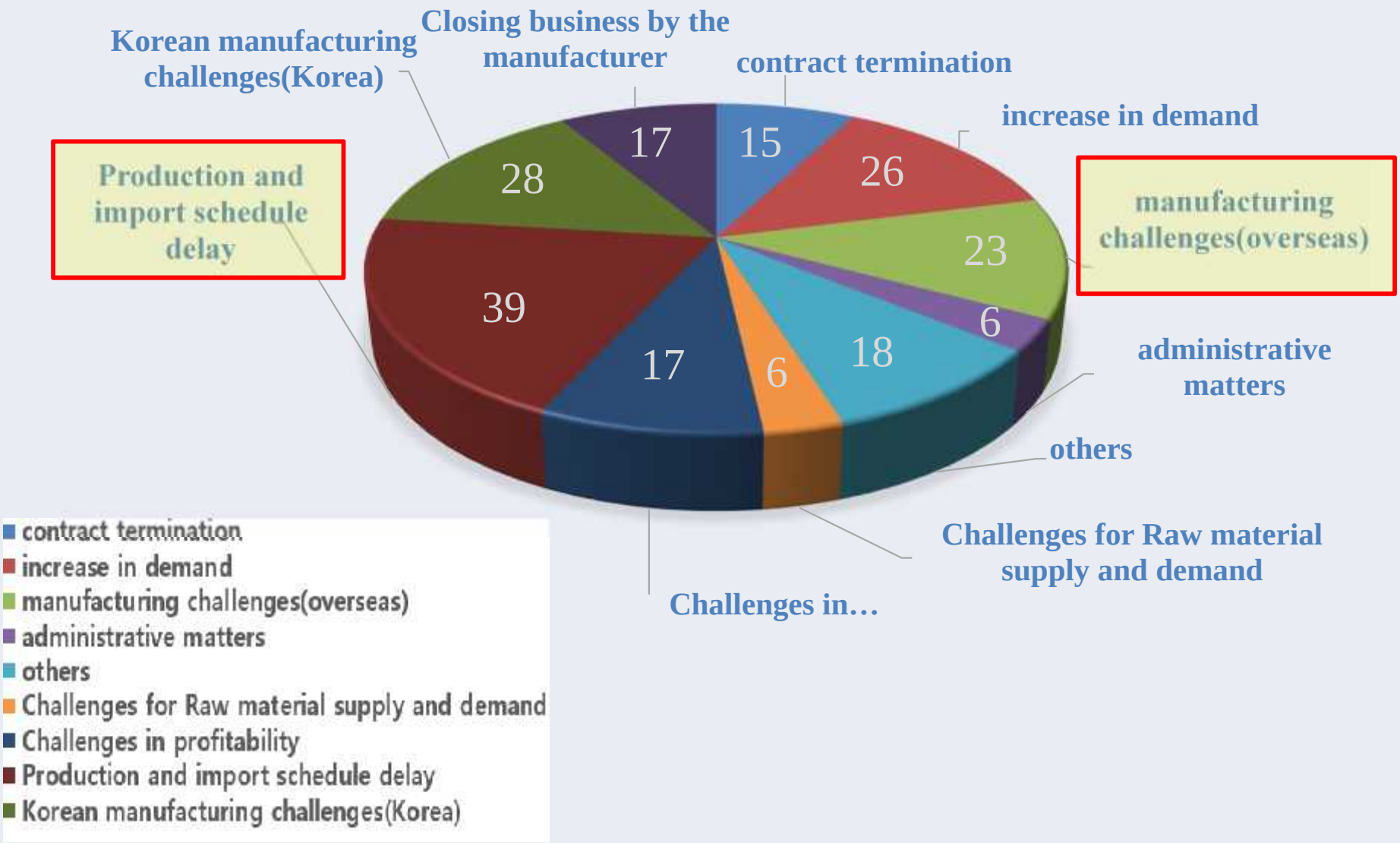
Landscape of Unstable Drug Supply and Demand in Korea

▣ Annual Number of Cases of Drug Supply Discontinuance



Landscape of Unstable Drug Supply and Demand in Korea

▣ Main causes of Drug Supply Discontinuance(as of 2022)



Policy to Stabilize Drug Supply

▣ **3 Strategies for Stable Drug Supply and Demand by MFDS**

Management of "Reporting Process of Discontinuance of Drug manufacturing, Import and Supply"

Operation of "On-Site Drug Demand and Supply Monitor ing Center"

Development of Prediction System for Drug Discontinuation of Supply

Reporting Process of Discontinuance of Drug Manufacturing · import · Supply

▣ Management of Reporting Process of Discontinuance of Drug manufacturing, Import and Supply

Not reported or reported **beyond the reporting date**

Have to report
the reason for the discontinuance

MFDS

at least 60 days
in advance

MFDS **can prepare** appropriate measure
prior to discontinuance of supply

Reporting Process of Discontinuance of Drug Manufacturing · import · Supply

▣ List of drugs to be reported

; that are expected to significantly impede patient care if supply is discontinued

about 4,000 drugs

▣ Reporting Details

- Product name
- Reason for discontinuance
- Expected date of discontinuance
- Current inventory
- Impact of discontinuance on treatment, etc.

Reporting Process of Discontinuance of Drug Manufacturing · import · Supply

▣ Next step

Pharmaceutical companies

① **report**
Discontinuance of Drug Manufacturing · import · Supply

MFDS

Sharing information

④ **Communicate the consultation**

KOEDC
Korea Orphan & Essential Drug Center

(if necessary)
⑤ **Take measures**

Urgent import of drugs from abroad

Administrative Support
(Limited Release, Postponement of API registration)

(effect on patients during the suspension of supply)
② **Request for advice**

(The effect on the patient is "serious", "uncomfortable", "minimum")
③ **Reply to Review**

Medical Expert Advisory Group

On-Site Drug Demand and Supply Monitoring Center

▣ Establishment of monitoring center to supervise drug supply

- **Background** : There is a need to share the status of drug supply directly at pharmaceutical companies, distributors, and **use sites**

- **Monitored subject : all drugs**

- **Composition : 7 pharmaceutical- related professional organizations**

KMA 대한의사협회 | 대한약사회 KOREAN PHARMACEUTICAL ASSOCIATION | (사)한국의약품유통협회 | 한국병원약사회 | KRPIA 한국글로벌의약산업협회 | KPBMA 한국제약바이오협회 | KoBIA 한국바이오의약품협회

- **Activities**

① Directly monitoring drug supply at the medical site

② Investigate the current status of monitored drugs

③ Provides information on the status of drug supply to those who report on drug supply instability, medical experts

On-Site Drug Demand and Supply Monitoring Center

▣ Next Step

① Monitor supply status

On-Site Drug Demand and Supply Monitoring Center

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⑥ Reply to Review

⑤ Request for advice

② Report drug shortage

KOEDC Korea Orphan & Essential Drug Center

Operating Monitoring Center, Collecting and investigating Information

③ Report meaningful drug shortage

(impact on patients during the discontinuation of supply)

④ Request for advice

⑦ Communicate the consultation

MFDS

Overseeing and Taking Countermeasures

(If necessary)

⑧ Take measures

Urgent import of drugs from abroad

Administrative Support
(Limited Release, Postponement of API registration)

Prediction System for Discontinuance of Drug Supply

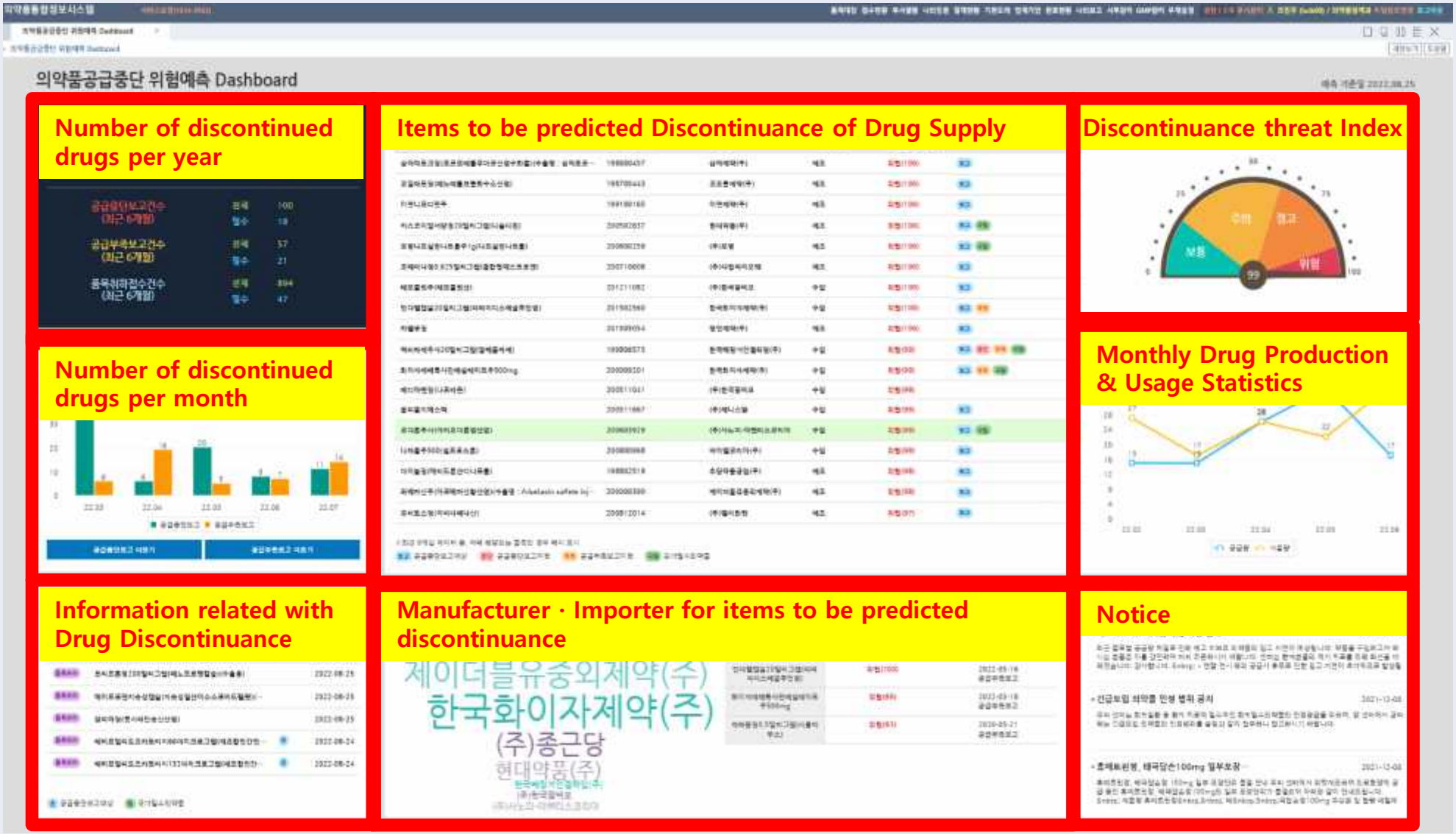
▣ Overview

- A system that **predicts discontinuance of drug supply** based on the analyzed the data on production(import) and Medication prescription.

Fortunately, our system is not an octopus!!

Prediction System for Discontinuance of Drug Supply

▣ Prediction Dashboard



Prediction System for Discontinuance of Drug Supply

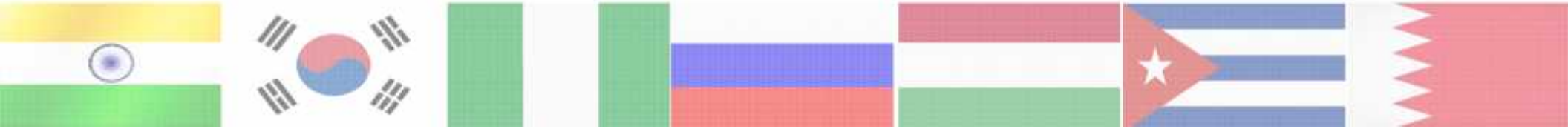
▣ Our Challenges

- (**2019**) **develop** the algorithm → (2020) establish this system → (2021~) has been operated

- ‘Items to be expected discontinuance of supply’ in the system **was not matched with the ‘actual shortage’**

- To improve the accuracy, the prediction system has been evaluated by adjusting evaluation variables or weights. Our milestone is to preemptively prevent discontinuance of drug supply by predicting the situation.

Thank you!!
(감사합니다)



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