Ministry of Food and Drug Safety

COVID-19 : MFDS's Experience

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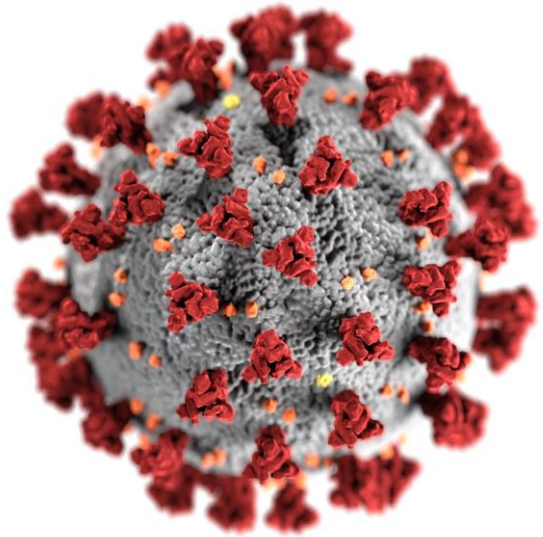
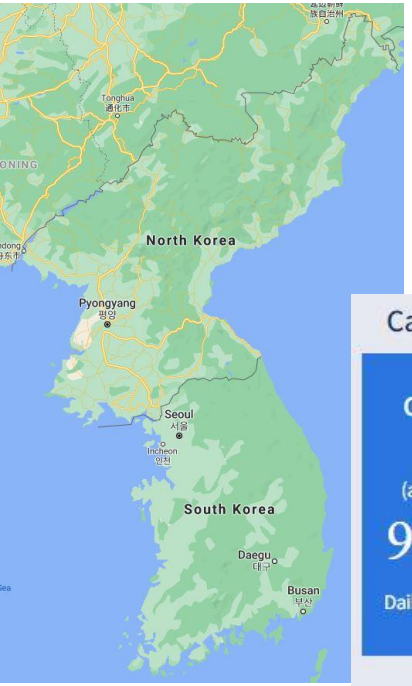


Feature of COVID-19 in Korea



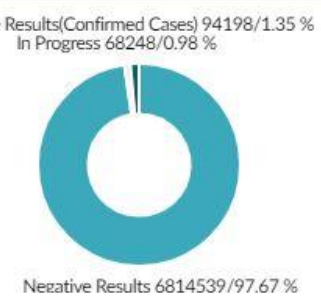
Cases in Korea (as of 12am on March 11, 2021, data aggregated from January 3)

Confirmed Cases (accumulation)	Released from isolation (Released from Quarantine)	Isolated	Deceased
94,198	84,675	7,871	1,652
Daily Change + 465	+ 363	+ 98	+ 4

Testing in Korea (as of 12am on March 11, 2021, data aggregated from January 3)

Tests Performed	6,976,985
Tests Concluded	6,908,737
* Positivity Rate	1.4 %

* postitive tests / total number of tests concluded * 100%



- One of countries affected early by COVID-19 pandemic
  - First infected case in Korea (20 January, 2020)
- Easy to restrict the inflow of population
- Establishment of a pan-government task force
  - Establishment of the Central Disease Control Headquarters (20 January, 2020)
  - Principle : Striking a balance between prevention and daily lives of the people
  - Countermeasure : 3T (Test, Trace, Treat)

COVID-19 Diagnostic Devices

■ Background

– Absence of In Vitro Diagnostic(IVD) medical devices intended to diagnose COVID-19

■ Response 1

– Emergency Use Authorization(EUA) issued for IVDs intended to diagnose COVID-19

* First infected case in Korea (20 January, 2020)

→ Authorization(EUA) issued for IVDs intended to diagnose COVID-19 (a total of 15 days taken, 4 February, 2020)

Categorization		Approval	
EUA(Molecular)		16	
Market authorization	Molecular	12	18
	Antigen -Antibody	6	
Medical devices for export only	Molecular	121	276
	Antigen -Antibody	155	
Total		310	

COVID-19 Diagnostic Devices

■ Response 2

– Official approval for medical devices approved for emergency use to be prepared for prolonged COVID-19 pandemic

* (April 2020) Provided support to expedite the approval process for reviewing COVID-19 diagnostic kits

  : Shorten period for the review and approval process

* Secured officially approved devices with the expedited approval process

“Guidance on the Review and Approval of In Vitro Diagnostic Devices for COVID-19 (March 2021) “

COVID-19 Diagnostic Devices

■ Response 3

– (Mar 2021) Measures for the review and approval process of diagnostic kits intended to detect

▲ **COVID-19 variants**

▲ **a neutralizing antibody against COVID-19**

■ Plan

– Introduction of measures for the review and approval process for at-home COVID-19 diagnostic kits

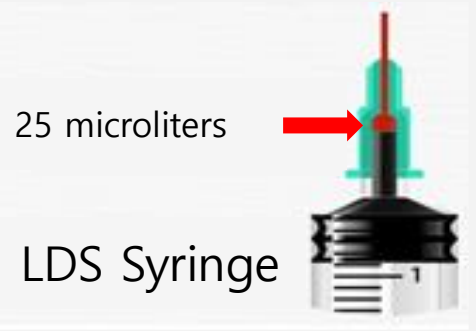
Low Dead Space(LDS) syringes

■ Background

– Increased need for the approval of LDS syringes by MFDS to increase the rate of vaccinations

■ Response

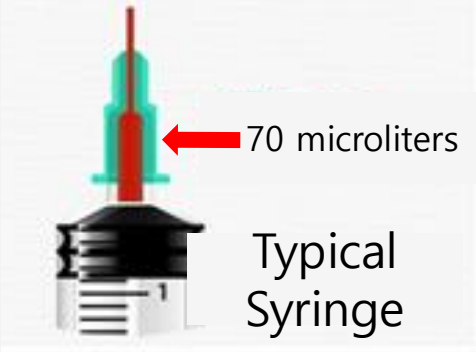
– Identified LDS syringes manufacturers in Korea and hold an emergency consultation (22 December, 2020)
– Submitted technical documents for review and made a change in the certificate (took 6 days, submitted on 31 December, 2020, completed on 6 January, 2021)
– First approval of LDS syringes in foreign markets(Feb. , 2021)



Previously — **25 days**

With support from MFDS — **3 days** — **22 days shortened**

In cooperation with MFDS, CAB, testing laboratories and other third parties



Medical Respirators

■ Background

- Due to the prolonged COVID-19 pandemic, medical respirators for healthcare providers are necessary
- Under the pandemic, it is necessary to boost domestic production of medical respirators to ensure a stable supply of medical respirators to healthcare providers

■ Response

- "Guidance on the Review & Approval of Medical Respirator" (August 2020)

  * Established international level criteria that allows typical respirator manufacturers to manufacture medical respirators

Flexible Operation of Inspection System

■ Background

- Hard to carry out on-site audit of manufacturers sites amid public concern over the spread of coronavirus
- The halt in regularly surveillance caused concern over quality deterioration of clinical trials

■ Response

- Transformation of on-site GMP audit of manufacturers into off-site documentation review (April 2020)
- Transformation of on-site assessment of clinical institutions into documentation assessment/voluntary assessment (July 2020)

* **It is important to note that on-site assessment may be necessary**

Transcendent Collaboration

■ Background

- Transcendent collaboration is necessary to tackle COVID-19 pandemic

■ Response

- **(Between governments in different jurisdictions)** Shared information on guidance and approved products necessary to fight COVID-19
- **(Between agencies)** Had a discussion about the development and supply of medical devices with MOHW, KDCA and other government agencies
- **(Between the government and private institutions)** Had a discussion about expedited approval process of protective equipment
- **(Between the government and the industry)** Had a discussion about the development of devices in consideration of increased need and expedited review and approval process

Lesson learned and Considerations

■ **Reaffirmed the importance of international cooperation**

- Enabled to have necessary information for prompt decision making through the international network of regulators (such as IMDRF) and with mutual trust

■ **Emphasized the importance of cooperation between stakeholders and involved organizations**

- Cooperative relation between manufacturers, testing laboratories, CAB and other government agencies is necessary to deal with expedited approval process and a supply shortage of medical devices

■ **Redefined the role of medical device regulator in a public health crisis**

- (In usual) Validation of the safety of medical devices
- (In crisis) Validation of the safety of medical devices and support for just-in-time delivery

“Special Act on Promoting the Development and Emergency Supply of Medical Products in response to Public Health Crisis(9 March 2021) “

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