Ministry of Food and Drug Safety

MFDS' Lessons Learned amid COVID-19

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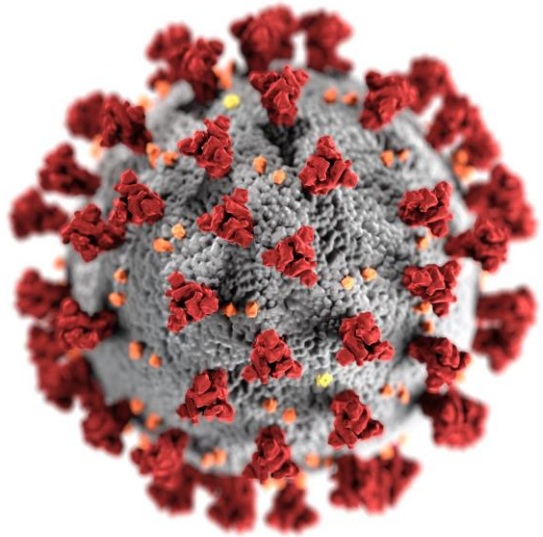
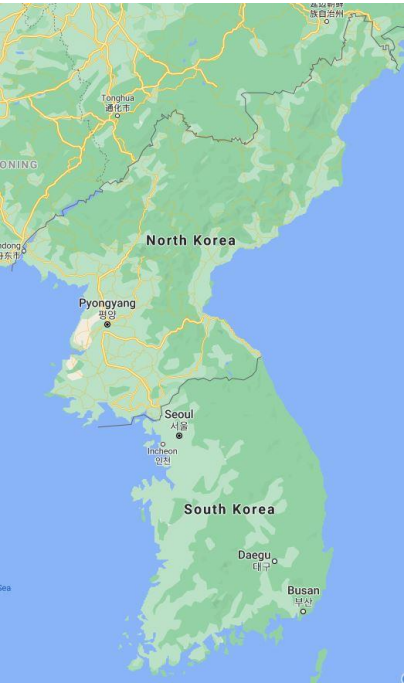
Oh-Sang Kwon

Director General
Medical Device Safety Bureau
Ministry of Food and Drug Safety
Republic of Korea



Early Stage to Respond to COVID-19



- One of the countries affected quite early by COVID-19
  - The first infected case occurred on January 20, 2020, in South Korea

- Establishment of a pan-government task force
  - Establishment of the Central Disease Control Headquarters as of January 20, 2020
  - Principle: Striking a balance between prevention and daily lives of the people
  - Countermeasure: 3Ts (Test-Trace-Treat)

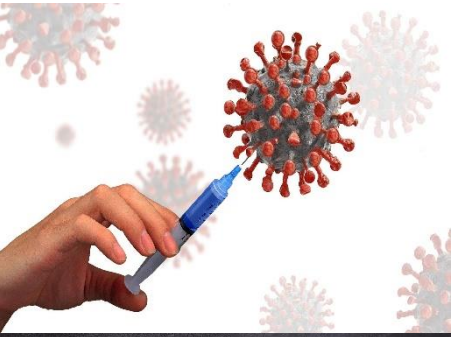
- EUA for the diagnostic test kits (1st authorization as of Feb 4, 2020 – 16th day after the first outbreak)
  - Production and exports loads skyrocketed for diagnostic test kits in 2020

    (production surged by 553% for IVD devices)

- Remote audits for GMP inspections (since February 2020)

COVID-19 Development in Korea

Delta



- Long-lasting impacts of continued COVID-19 spread
  - Managed delaying the domestic outbreak as late as possible
  - Continued increase of confirmed cases following the surging Delta variant

- Response strategy shifts by virtue of COVID-19 vaccinations
  - To prevent and control the virus by eliciting antibody responses in addition to diagnostics and quarantine
  - To procure the vaccines and medical devices used with the vaccines

- Increasing burden to people while extending distancing measures
  - People feel exhausted from prolonged social distancing

Back to Normal – Diagnostic Medical Devices

- Need for diagnostic test kits for early diagnosis in the course of COVID-19 treatment
  - 9 emergency use tests approved, shortening the time for test results (3 hours → 80 mins)
- Advanced performance of the test kits and various test methods
  - Review support as diverse test approaches emerge, using a nasal swab or capillary blood samples (approx. 30% of the review period shortened in average)
- Regulatory support for market authorization of the test kits
  - Support for mass production of molecular diagnostic tests and its raw materials
  - Assistance in market authorization subsequent to the development of point of care test kits (shortening the waiting period of testing results with the simple instructions)
- Sustainable supply of diagnostic test kits
  - EUA-granted IVD devices become invalid (Feb 3, 2021), and the 1st official approval (Aug 31, 2020)
  - 61 official approvals (28 Genetic, 19 Antigen, and 14 Antibody tests) as of Aug 31, 2021 (approx. 1.8 million released per week)
  - Keep monitoring domestic distribution chains, investigating produced or imported article volumes

Back to Normal – Medical Equipment

- Adequate support for syringe manufacturers for COVID 19 vaccinations
  - Quality management assistance for 7 manufacturing facilities (since April 2021)
    → used to be capable of producing 870 thousands at 4 sites per day (as of April this year)
    → became capable of producing 1 billion and 220 thousands at 7 sites per day (gov-initiated contracts)
  - e.g., give advice on the current facilities and the applicable resolutions like clean room setting, splitting up personnel and material traffic to avoid cross contamination, data analysis on foreign substance, and so forth
- Sustained supply of syringes for stable COVID-19 vaccinations
  - Handling products loads and overseeing supply timeline to sustainably meet the demand
- Rationing health care by setting up medical products in hospitals treating COVID-19
  - Mobilizing more beds and ECMO support in the right place at the right time for severe confirmed cases (including equipment repurposing as well)
- Enhanced safety management for COVID-19 related devices like thermometers
  - Sampling inspections for 22 non-contact thermometers (20 complied, and 2 under inspections)
  - Sampling inspections for 6 biopsy tools (1 complied, and 5 under inspections)
  - Sampling inspections for 14 surgical gloves (9 complied, and 5 under inspections)

Back to Normal – Safety Paradigm Shifts

- Conducting paper inspections and remote work procedure
  - Remote audits for QMS certification (until December 2021); inspections done for 413 facilities
  - Actively using virtual consultations during review and approval process for medical devices throughout the year, and had online policy briefing sessions in February 2021
  - Planning to have a new framework to manage medical devices for remote medical treatment and therapeutics

- Flexible clinical performance studies system for COVID-19
  - By allowing hospitals to conduct diagnostic test trials which are not one of the designated institutions for clinical performance tests of IVD medical devices, on patients with coronavirus quarantined (since June 1, 2021)

Back to Normal – To Combat Future Pandemics

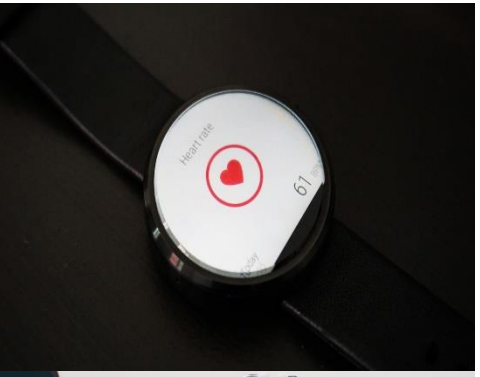
- Establishment of the Act on medical products to respond to crisis on public health (March 9, 2021)
  - Legal basis for prompt development of the relevant medical products and their emergency use for agile response to possible future pandemics that impact the public health to combat the crisis
  - Planning to designate the applicable medical products to address the hardships and designate preliminary medical products to tackle the future crisis prior to it (when applicable)
  - Planning to have the subordinates to set forth details on priorities to be reviewed in advance, and parallel submissions review on demand (October 2021)

- Network constructed for clinical performance evaluation for IVD devices
  - Linking entities to healthcare institutions for clinical performance evaluation support for test kits (11 cases)
  - Pan-government portal website to share information on the current sample stocks

- Capacity building for crisis preparedness to respond to the pandemic
  - Support for clinical investigations and GLP studies for development of therapeutic products and vaccines for COVID-19 (approx. 140 billion in 2021)

  → To drive local development of therapeutic products and vaccines for COVID-19

Back to Normal – Personal Health Care



- Expansion of personal health care area
  - Sudden increase of using thermometers in domestic market
    (386,530 produced in 2020 → 23,206,725 produced in 2020)
    : routine practices for addressing personal symptoms like body temperature in daily lives
  - Accelerated towards personal healthcare using wellness devices
  - Push ahead with clarifying borderline products in grey area and their quality management

- Preemptive actions needed to be aligned with the development of new types of medical devices

  * SaMD in global market, as of 2018, 37 trillion won (Korean dollar) → 130 trillion won, as of 2023

  - Rapid increase of developing therapeutic products with new technologies
    (e.g., software using virtual augmented technology for surgical procedures simulation on screen)
  - Need to pave the way for thriving industry by developing guidelines on decision making of medical devices and guidelines for review & approval
  - Essential cyber security to keep high-level protected data as digital therapeutics are blooming
    (e.g., recalls of implanted medical devices due to cyber hacking risks)

Back to Normal – Information Sharing

- To strengthen agile approach to quick transformation of COVID-19 aspects
  - By Swiftly acquiring the accurate information
  - Through Communications with the related public and private sectors to exchange information
  - Using Bilateral and multilateral global communications and interchanges

- To have ongoing and persistent channel to exchange information
  - Sharing simple information: safety info. or current approvals in each jurisdiction, and so forth
  - Exchanging somewhat in-depth details: relevant information like criteria to review the products
  - Rather efficiently accomplished through the existing fora (e.g., IMDRF)

IMDRF International Medical Device Regulators Forum

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