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The Ministry of Food and Drug Safety Provides Support for COVID-19 Treatment/Vaccine Development and Stable Management of Drug Supply

- Priority/quick review of clinical trial plans for the development of COVID-19 treatments
- Management of drug supplies for COVID-19 treatments, such as through special import

- The Ministry of Food and Drug Safety (Minister Lee Eui-Kyung) has been supporting the quick development of COVID-19 treatments/vaccines and ensuring the stable supply of drugs used to treat COVID-19.

- [1] **Support for COVID-19 Treatment/Vaccine Development**
 - **Support for Commercialization**, including development consultation
 - **Priority/quick reviews** on clinical trial plans
- [2] **Government-wide cooperation on COVID-19 Treatment Development Project**
- [3] **Stable Supply Control of COVID-19 treatments**
 - **Special import** for drugs without domestic approval
 - **Monitor supply status of** drug manufacturers/importers

* **Clinical trial:** A test performed on human subjects which confirms the efficacy of a drug and checks for any adverse reactions to prove the drug is safe and effective.

«Support for COVID-19 Treatment/Vaccine Development»

- The MFDS has constructed a **commercialization team** (Feb. 3) within the Headquarters for COVID-19 emergency response support and is providing **support for commercialization** by operating a separate **consultation window*** for pharmaceutical companies planning to develop COVID-19 treatments/vaccines while also performing **priority/quick reviews** on **clinical trial plans**.

※ You can make inquiries by calling the “**commercialization team**” (043-719-2912) or can make a reservation through the “**integrated consultation reservation**” system on the MFDS website.

- As of the present, a total of **11 applications** have been submitted for COVID-19-related clinical trials, and after consultations with experts from the Korean Society of Infectious Diseases, the Korean Society for Antimicrobial Therapy, and other organizations, **5 among them have been approved**. (As of Mar. 26)

<Clinical Trial Approval Status>

- ▶ 3 clinical trials (Mar. 2, Mar. 5) regarding “**Remdesivir**” (Ebola treatment)
- ▶ 1 clinical trial (Mar. 20) regarding “**Kaletra tablets**” (HIV-1 infection treatment) and “**hydroxychloroquine tablets**” (malaria treatment)
- ▶ 1 clinical trial (Mar. 25) regarding “**hydroxychloroquine tablets**” (malaria treatment)

- Furthermore, the MFDS granted approval for **6 clinical trials** to allow **drugs currently under clinical trials** as influenza treatments **to be used for COVID-19 treatment**, and **10 more such approvals are being reviewed**. (As of Mar. 26)

※ **Approval for use in treatment purposes:** A system allowing **investigational drug** which have not yet received approval as pharmaceutical products to be used, after receiving special approval from the MFDS, for the purpose of treating **emergency patients whose lives are at risk or for whom there are no alternative means of treatment**, etc.

- Furthermore, we have prepared a “**guidance for COVID-19-related clinical trials**” and **have shared it with** the Korean Association of Institutional Review Boards (KAIRB), etc., so that approved **clinical trials can be carried out swiftly**.

* Main content:

- ① **Priority reviews of COVID-19-related clinical trials** at institutional review board (IRB)

- ② **Review carried out using non-face-to-face methods**, such as videoconferencing
- ③ Allowing consent to be given by clinical trial subjects through explanation over the phone, in consideration of quarantine measures, etc.

«Governmental COVID-19 Treatment/Vaccine Development Project Cooperation»

- The MFDS is **contributing to the COVID-19 treatment development projects** promoted by the Ministry of Science and ICT and Korea Centers for Disease Control and Prevention and is thereby **providing support to accelerate such development as much as possible.**
- We plan to **share information** related to clinical trials **from the early stages of development** and **review scientific feasibility**, thereby providing support to eliminate trial-and-error

- ▶ **Ministry of Science and ICT:** Implementing a **Drug Re-purposing Project** to discover drugs approved by the USA’s FDA which are effective at treating COVID-19 then deliver research results to the medical community and enable them to be used clinically
- ▶ **Korea Centers for Disease Control and Prevention:** Expand the scope of use of existing medications for the development of COVID-19 treatment, launch clinical trial research projects related to antibody treatments/plasma treatments/vaccines

«Managing Supply of Drugs Used to Treat COVID-19»

- **Special import** of drugs which are not approved domestically is being carried out when the Korea Centers for Disease Control and Prevention requests it for the sake of **treating COVID-19.**
- Accordingly, the **3 cases of special import** have been allowed for “**Kaletra solution,**” an HIV-1 infection treatment which has not been approved for use in Korea.
 - ※ **Special import:** A system allowing **drugs which have not received an item approval to be imported in cases where the head of a related governmental department makes such a request for preparing for an infectious disease pandemic**, etc. (Item approval is normally required to import a medication)

- Furthermore, the status of **the domestic supply** of **“Kaletra” and “hydroxychloroquine tablets,” etc.** being used to treat COVID-19* **is being monitored**, to thereby ensure we are prepared to import or produce these drugs if needed.

* Based on expert recommendation regarding drug treatments for COVID-19 (Mar. 13 2020, The Korean Society of Infectious Diseases, etc.)

- Currently, businesses in Korea have secured **“Kaletra tablets” enough for around 15 thousand people and “hydroxychloroquine tablets” enough for 200 thousand people** (as of Mar. 26).

- The MFDS pledges to provide **continuous support** to help **COVID-19 treatments/vaccines be developed quickly** and closely cooperate with related governmental departments such as the Korea Centers for Disease Control and Prevention to **stably control the supply of drugs used to treat COVID-19**, making sure **a sufficient supply** is given to the **medical sites** that need them.