Office liaison 2020 March 19

Within each prefectural health department (Bureau)

Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare
Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

Handling of Notifications of Clinical Trial Plans Related to Pandemic Coronavirus Infection

Since this new coronavirus infection is a disease that can seriously affect life and health, and there are no drugs, etc. for which efficacy has been verified, the handling of drugs, machinery, etc. or processed cells, etc. that need to be used urgently (hereafter referred to as "drugs, etc.") in terms of clinical trial initiation without delay will be handled as follows for interpretation.

Notation

Article 80-2, Paragraph 3 of the Law Concerning the Assurance of Quality, Efficacy and Safety of Drugs and Medical Devices (Law No. 145, 1960) stipulates that "A person who has submitted a notification pursuant to the main clause of the preceding paragraph (limited to the person who has submitted a notification pursuant to the provisions of the same paragraph for the first time for drugs, etc. subject to clinical trials pertaining to said notification) shall not sponsor a clinical trial or conduct a clinical trial on his/her own until 30 days have elapsed from the date of said notification. In this case, the Minister shall conduct necessary investigations to prevent the occurrence of health and hygiene hazards with regard to the clinical trial plan pertaining to said notification."

In view of the purpose of Article 2, Paragraph 2, and Paragraph 3, drugs required for the control of pandemic coronavirus infection that have been investigated as specified in Article 3, may be started without waiting 30 days after the clinical trial plan has been notified.

End of notification