

PMDA pledge to tackle COVID-19 Pandemic

31st March, 2020

Since the WHO declared a Public Health Emergency of International Concern in January 2020, the COVID-19 pandemic calls out to the world to respond efficiently and urgently. The PMDA, working together with the Ministry of Health, Labour and Welfare, MHLW, has expeditiously responded to this public health threat and emergency. As part of our commitment to promote access to innovative medical products to the public, the PMDA facilitates the development of medical products for COVID-19. Here I would like to share important steps the PMDA has taken to address this global health threat.

1. Close interaction with sponsors

Our staff have worked closely with sponsors to further streamline the development of products for COVID-19. Countless meetings on specific products were held to discuss, and ensure the efficient development of products. The discussions continue in the coming weeks to further expedite product development, accelerating the delivery of products crucial in combating the coronavirus outbreak.

When facing situations where some clinical trials were not performed as originally planned due to extraordinary medical situations, the PMDA provided sponsors with opportunities to consult relevant review offices to deal with diversions from the clinical trial protocol, and supported them to find other effective measures.

2. Clinical trials start without waiting for 30 days

Under the Administrative Notice issued by the Pharmaceutical Evaluation Division and the Medical Device Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau of the MHLW on 19th March, 2020, the PMDA now allows sponsors of candidate products for COVID-19 shorter clinical trial notifications (CTN) timelines in starting first in human clinical trials. The submission of CTN by the clinical trial sponsor to the PMDA on their plans is required 30 days prior to its planned starting date under normal circumstances. This Administrative Notice allows the sponsor to start clinical trials of COVID-19 candidate products without waiting for 30 days, as long as the required review of the clinical trial plan to safeguard public health can be completed by the PMDA. Currently, several CTNs for clinical trials for COVID-19 are being submitted and processed expeditiously.

All these efforts, among others, not only expedite development of products for COVID-19, but also provide the people affected with a variety of investigational medical products. Once these products are approved, there will be more options for people around the world to prevent, diagnose and treat COVID-19. The PMDA continues to ensure that candidate products are safe and effective with reliable qualities. We will also continue our collaboration with other regulatory authorities to tackle this unprecedented threat and to protect global public health.

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