Pharmaceuticals and Medical Devices Agency (PMDA)
独立行政法人　医薬品医療機器総合機構

Four IVDs Approvals for COVID-19 and Response to the Increased Ventilator Demand

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It is essential for the PMDA to communicate and cooperate with stakeholders including product developers, academic researchers and other government partners efficiently when there is an urgent need for medical products, like the case we are facing with the COVID-19 pandemic. Since the outbreak of COVID-19 was noticed, we have been reaching out to these stakeholders to facilitate development of, and thus faster access to, products that may prevent, diagnose or treat COVID-19. Today, I would like to announce recent advancements in Japanese regulator's effort.

1. Four In Vitro Diagnostics received marketing authorization

By 20th April, four In Vitro Diagnostics (IVDs) to be used for PCR assay were approved with marketing authorization of Pharmaceuticals and Medical Devices Act in Japan for the detection of the novel coronavirus. These diagnostic tests all underwent complete assessment by the PMDA reviewers for analytical performance. This means that patients and health care professionals can rely on the test results obtained by these products with strong confidence, and physicians can select the most appropriate care for the patient. These products were made speedily approved by close and timely interactions between the product developers and the PMDA, utilizing scientific advice meetings.

In addition, in accordance with the Administrative Notice issued on 13th April by the Pharmaceutical Evaluation Division and the Medical Device Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau, MHLW, the PMDA now prioritizes review, inspection and other necessary operations for products for COVID-19. In this context, the PMDA now accepts most of the documents to be submitted by postal mail, email or electronically and consultation meetings to be held by online or in writing during this pandemic. These our efforts will be all enabled to assist faster access to products for patients of COVID-19.

2. Interactions and clarification for ventilator manufacturers

On 13th April, a series of Administrative Notices were issued by the MHLW aiming at securing and boosting supplies of ventilators in response to its increased demand from the spread of COVID-19. They outline how companies that are manufacturing or planning to manufacture ventilators, such as automobile companies, can bring products to the market quickly. They clarify required regulatory procedures, whether the company manufactures only some parts or assemble the products. It also gives the manufacturers information on which MHLW division to contact depending on the subject matter in relation to ventilator supply. In addition, the PMDA published a series of reminders to health care professionals on its website to encourage safe use of medical devices used to care COVID-19 patients, including Precautions in Ventilator Use, Precautions in Handling Tracheal Tubes, and Precautions in Bedside ECG Monitoring (Reminder Series No. 1, No. 2, and Revised No. 29, respectively). Combined with early interactions already provided by the PMDA, more regulatory support is now available for ventilator manufactures to deliver this critical devices to the clinical setting, and they are ready to be used in a proper manner on site. These Administrative Notices with its summary is available here in Japanese.

Arranging every necessary support for product developers/manufacturers to deliver safe and effective products for COVID-19 with good quality is of utmost importance

now. By offering rational and flexible regulatory support, the PMDA, working together with the MHLW, continues to support companies to develop and/or provide promising products for those who are fighting against this crisis at the front line.

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