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

Special Approval for Emergency on First COVID-19 Vaccine in Japan

16th February, 2021

On 14th February, the first COVID-19 vaccine applied by Pfizer Japan Inc. was granted Special Approval for Emergency in Japan. With this Special Approval for Emergency, Japanese citizens can now start vaccination with prioritization to protect themselves against SARS-CoV-2.

Special Approval for Emergency is the process under article 14-3 of the Pharmaceuticals and Medical Devices Act in order to approve a medical product swiftly in an emergency situation to protect public health. This regulatory process was also utilized in the authorization for Remdesivir in May, 2020.

Pfizer Japan Inc. submitted the COVID-19 vaccine application on 18th December, 2020, and the PMDA's review team had been assessing the data tirelessly since then. This vaccine was aligned to the concept of Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2 published by the PMDA in September last year. Based on results of Japanese and foreign clinical trials, Special Approval for Emergency was granted to this vaccine.

While these data were carefully reviewed, intensive post-approval activities are

planned to be carried out. For example, all cases of vaccination to 10,000-20,000 healthcare workers, who are prioritized to receive vaccination first, will be followed up for symptoms and illnesses for about 1 month after vaccination. In addition, post-vaccination health status survey will be conducted in a questionnaire form in general vaccine recipients with prior informed consent. Results of these activities and other routine post-approval measures will be released publicly once available.

Vaccination against SARS-CoV-2 is now ongoing around the world, and new data are being generated day by day. In this circumstance, it is essential for regulatory authorities to collaborate in gathering, sharing, assessing and disseminating the latest information. The PMDA will cooperate with various stakeholders including other global regulatory authorities, healthcare workers and vaccine recipients and continue the vaccine's safety measures towards Japanese citizens' sound health.

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