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

PMDA Reveals Principles on Evaluation of COVID-19 Vaccines

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The COVID-19 pandemic remains a serious threat to global health, and a vaccine agaist SARS-CoV-2 is urgently needed to prevent further its spread. Efforts to develop vaccines are being made by many vaccine companies and academic research organizations around the world. The PMDA commits its responsibility to secure access to quality, safe and effective vaccines to be developed in a timely manner and has taken several actions with regulatory agility, including free-charged scientific advice for COVID-19 vaccines development as introduced in my previous statement. In addition to those actions, the PMDA has revealed “Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2”.

This document addresses specific regulatory considerations and provides necessary information for development of COVID-19 vaccines covering wide development stages and aspects. And it should be utilized with other information available for development of COVID-19 vaccines such as Administrative Notices, guidelines by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and approaches proposed by the International Coalition of Medicines Regulatory Authorities (ICMRA).

In this PMDA’s principles, it is recommended that efficacy of COVID-19 vaccines is

in principle evaluated using the disease-preventive effect as the primary endpoint, and clinical trials to assess the effect against COVID-19 must be conducted, since no surrogate marker (a measure intended to substitute for a clinical endpoint) for the effect is currently known. For evaluation of safety, it is required to collect adverse events (AEs) of solicited local and systemic reactions observed during the first at least 7 days after administration of the SARS-CoV-2 vaccine candidate as well as AEs observed during the first at least 28 days after administration. In addition, disease enhancement risk from vaccination should be assessed in clinical trials, and such clinical trials need to be conducted with necessary measures for the theoretical risk, such as appropriate procedure of informed consent and careful safety follow-up of subjects. Also, considerations when including subjects of specific population groups such as the geriatrics and pregnant women/nursing mothers into clinical trials are noted in this document.

I would like to express my gratitude to all who contributed to development of this Principles, including experts from the National Cancer Center Hospital, the National Institute of Infectious Diseases, and other academic institutions. Regulatory considerations discussed by global regulatory authorities within the ICMRA, which I serve as vice-chair, were also taken into account. Especially, those discussed in March and June significantly contributed. Integrating global approach into national principles and international cooperative schemes like the ICMRA are truly valuable when we fight against the unknown threat like COVID-19. To bring an end to this novel coronavirus outbreak, the PMDA continues to join forces nationally and globally.

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