

## **PMDA to Offer Free Scientific Advice for COVID-19 Vaccines Development**

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Ensuring access to vaccines against the SARS-CoV-2 (novel coronavirus) is the most pressing challenge in global health, considering the confirmed number of COVID-19 cases reaching 35 million globally. Over the last few month, the PMDA has taken many actions to address this crisis, including swift approval of treatment, diagnostic tests and medical devices for COVID-19, active engagement in global cooperation, and early interactions and regulatory support to product developers. Today, I would like to introduce additional support by the PMDA to help efficient development of COVID-19 vaccines.

On 1<sup>st</sup> October, the PMDA started to offer free of charge scientific advice meeting for the development of COVID-19 vaccines. In this meeting, vaccine companies and academic research organizations can discuss on overall development strategies including clinical trial protocols with PMDA reviewers of relevant offices, depending on the topics to be discussed. More information and related forms are available [here](#) in Japanese.

With early engagement of PMDA reviewers in vaccine development through this meeting, it is expected to enhance predictability of vaccine development against the SARS-CoV-2, and to facilitate early initiation of clinical trials. In addition, the PMDA

[published](#) the “Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2” on 2<sup>nd</sup> September, presenting basic principles concerning the efficacy and safety evaluation of COVID-19 vaccines in Japan. Together, they would function as strong tools to help vaccine developers advance their development further and faster. In this way, the PMDA continues to provide unconventional approaches to facilitating early patient access to medical products necessary to tackle COVID-19 pandemic thus ultimately protecting public health.

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