

To the press

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Establishment of PMDA Washington, D.C. Office - as First US Base -

The Pharmaceuticals and Medical Devices Agency (PMDA: Dr FUJIWARA Yasuhiro, Chief Executive) announced today that the PMDA Washington, D.C. office (Head of the Office, Dr ISHIGURO Akihiro) had been established, which is the first PMDA's U.S. office, dated November 1, 2024. This is our second overseas office after the Asia office that we established in Thailand in July.

As more and more innovative drugs are being developed by overseas start-ups (especially in the U.S.), such drugs are needed to be developed rapidly also in Japan.

To work on the issue, the PMDA decided to establish the office in Washington, D.C. In the office, we will promote enhancement of pharmaceutical regulatory cooperation and information exchange on regulations with administrative organisations in the U.S., including the U.S. Food and Drug Administration (FDA) on site. And for start-ups which locate in the U.S., we will provide the information regarding Japanese regulations on reviews and post-marketing safety measures, as well as offer the services including early general development consultation and related services. We believe that these measures will support to promote the development of innovative drugs and medical devices in Japan, contributing to making everyone's lives brighter together.

Dr ISHIGURO Akihiro who takes office as a Head of the Office today says that "I would like to contribute so that the PMDA, as one of the three major regulatory agencies, can play a role as a bridge in developing innovative drugs and medical devices in Japan and the U.S. rapidly, and to making innovative products that patients expect available earlier in Japan".

The establishment of the Washington, D.C. office contributes to realization for development of the PMDA overseas offices in proceeding of "enhancement of ability to make international contributions and proposals", one of the directions to perform the PMDA's 5th mid-term plan.

The significance of the office was also stated in the Joint Leaders' Statement of the Japan-U.S. Summit Meeting and its fact sheet in this April, which expressed expectations for role of the Office.

(Reference: Location of the PMDA Washington, D.C. office)

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