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

News Release

2nd October, 2017
(Contact) Junko Sato,
Office Director,
Office of International Cooperation
(Tel) 03-3506-9456

EMA Staff Fellowship Program Introduced

The Pharmaceuticals and Medical Devices Agency (PMDA) and the European Medicines Agency (EMA) have been working together and sharing information to ensure the quality, efficacy and safety of drugs, and to contribute to improved medications for people. This includes providing development consultations (scientific advice) and reviews (scientific opinions for pre-market approval) at the pre-market stage, as well as the collection, analysis and distribution of safety information at the post-market stage in Japan and Europe, respectively.

PMDA and EMA are leading and promoting regulatory harmonization and international collaborations through various organizations such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) to address globalization of drug manufacturing and supply. To build on the experience of scientific communications between both agencies, **a new program called 'EMA Staff Fellowship Program' has been agreed and is introduced as of October 2017**.

The program allows regular opportunities for **EMA staff to be dispatched to Japan for 2 to 3-week intensive discussions of pre-identified specific projects.** This program is expected to bring deeper mutual understanding, effective collaborations in strategic areas, promotion of regulatory science, and sharing of successful experiences between agencies.

The first EMA official will join PMDA from 12th to 27th October 2017. The project is about procedural aspects of drug assessment, from the pre-market stage to the post-market stage. The exchange of experience and opinions will include not only relevant offices in PMDA, but also the Ministry of Health, Labour and Welfare, and other stakeholders in Japan. Subsequently, there are plans for other EMA officials to visit the Japanese Regulatory Authorities, which will result in implementation of several different projects.

Through this program, PMDA and EMA will establish a stronger relationship and contribute to advancing access to appropriate drugs for both Japanese and European patients.

This activity is aligned with PMDA's International Strategy 2015 and the EMA and EU network strategy to 2020.