PMDA NEWS RELEASE

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Media Inquiries: Kyoichi Tadano, +81-3-3506-9456

Title: The Second China - Japan Symposium on Drug Development focusing on IND, Pre-Consultation, GMP and DMF system

PMDA co-hosted “The Second China - Japan Symposium on Drug Development focusing on IND, Pre-Consultation, GMP and DMF system” on March 29 in Beijing, with the China Centre for Pharmaceutical International Exchange (CCPIE) and the Japan Pharmaceutical Manufacturers Association (JPMA,), supported by R&D-based Pharmaceutical Association Committee (RDPAC.) The symposium was realized as one of a series of bilateral efforts to enhance the cooperative relationship between China’s State Food and Drug Administration (SFDA) and Japan’s Ministry of Health, Labour and Welfare (MHLW) and PMDA. It was PMDA’s first major international activity outside of Japan after the 2011 Tohoku-Pacific Ocean Earthquake, which hit northeastern Japan on March 11.

Mr. Zhang Wei, Director General of the Department of Drug Registration, SFDA and Dr. Toshiyoshi Tominaga, Director of the Office of International Programs, PMDA delivered key note speeches. Mr. Zhang discussed the latest progress of Chinese drug registration management, and Dr. Tominaga delineated PMDA’s efforts for China-Japan cooperative relationship. At the beginning of his presentation, Dr. Tominaga conveyed a message from Dr. Tatsuya Kondo, Chief Executive of PMDA, on 2011 Tohoku-Pacific Ocean Earthquake that PMDA would continue its efforts to overcome the current hardship.

Then he presented how PMDA promoted cooperation with SFDA, emphasizing the significance of holding the symposium continuously. He stated, “In order to facilitate developing new drugs in Asia and put them on the global market for patients around the world, it is essential for East Asian countries to work together with mutual trust. Particularly, PMDA recognizes the China-Japan relationship as one of its top priorities in international activities.”

The main topics of the Symposium were; a) IND system and Pre-consultation system, b) GMP and c) Drug Master File (DMF) system. The speakers from SFDA, RDPAC, PMDA, and JPMA explained the systems employed in each country and expressed their views on them from their respective positions. The Panel Discussion, which dealt with DMF and GMP issues, offered opportunities for the audience to discuss realities and expectations on how the relevant regulations are implemented in each country.

The symposium had more-than-expected 180 attendees, which showed a high interest in the issues as well as the future of Sino-Japanese cooperation.