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PRESENTATION ABSTRACT

Title: Japanese Pharmacopeia Update

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Abstract: First Japanese Pharmacopeia (JP) was published on June 25, 1886 and implemented on July 1, 1887. JP is published by the Ministry of Health, Labor and Welfare (MHLW) in accordance with the Pharmaceutical Affairs Law. Pharmaceuticals and Medical Devices Agency (PMDA) is a semi-governmental Agency (incorporated Administrative Agency) which was established on April 1, 2004. PMDA mainly conducts all the scientific and technical evaluations and reviews on pharmaceuticals and medical devices and plays substantial roles in establishing JP. MHLW organizes JP committee under the Pharmaceutical Affairs and Food Sanitation Council and PMDA organizes JP expert Committee including a sub-committee and working groups. About 150 experts belong to National Institutes, Universities and representatives from Tokyo and Osaka Pharmaceutical Manufacturers' association. JP expert committee has 13 sub-expert committees. Main policies on the preparation of JP16 are 1.addition of monographs important for health care and medical treatment, 2.active introduction of up-to-date science and technology, 3.promotion of international harmonization, 4.swift and timely partial revision and 5.ensuring transparency of the revision process and promotion of JP and public. Supplement II on JP15 will be published on the end of September 2009. 106 new monographs will be added and one monograph will be deleted. 122 monographs will be revised. JP expert committee will make the effort to publish the Japanese Pharmacopoeia sixteenth edition on March 2011.